Contraceptive Procurement Manual

Government of Pakistan

Government of Pakistan

Ministry of Health

PLANNING COMMISSION

Contraceptive Procurement Manual

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Foreword

The Contraceptive Procurement Manual is provided as a tool for the Population Program Wing, Planning & Development Division, Ministry of Health, Population Welfare Departments and Departments of Health personnel who are tasked with the responsibility of procuring contraceptives of good quality on the international market to support Government of Pakistan Family Planning and Reproductive Health Programmes. The Contraceptive Procurement Manual is based upon best international procurement practices that promote transparency, accountability and efficiency in the procurement process. The Procurement Manual addresses the key phases of the procurement cycle, from procurement planning and issuing invitations to bid, to bid evaluation, supplier selection and contract award and management. It provides step-by-step instructions for desk officers and other hands-on procurement staff who are tasked with the responsibility of procuring quality contraceptives. It also provides pertinent information for midlevel decision makers and general guidance for heads of procuring units on how to best support the procurement process for contraceptives.

The manual also includes supplementary materials, such as information on pre-qualification and pre-shipment compliance that are designed to support the effective implementation for public sector procurement of contraceptives.

The Procurement Manual has been reviewed by key national stakeholders, including representatives from the Ministry of Population Welfare before devolution, the Ministry of Health and provincial Population Welfare Departments to ensure that it meets their requirements and needs. The manual also ensures compliance with the Public Procurement Rules of 2004 and the Public Procurement Regulations of 2008.

We would like to extend our appreciation to USAID Pakistan for providing financial support to the USAID | DELIVER PROJECT for development of the Contraceptive Procurement Manual. The use and application of the procurement procedures described in this manual by the responsible procuring agencies will help ensure that the people of Pakistan have access to quality contraceptive products that will best support their decisions regarding Healthy Timing and Spacing of Pregnancy.

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Acknowledgements

The Contraceptive Procurement Manual of Pakistan has been developed with the support of all relevant stakeholders. We gratefully acknowledge their dedicated efforts in reviewing, contributing to, and supporting the development of the manual.

We express our deep sense of appreciation to the technical experts in the field of procurement from government agencies and organizations who formed the key stakeholder review group. This group convened on several occasions to provide valuable comments and suggestions for revising and strengthening the contents of the manual keeping in mind the ongoing devolution. The manual ensures that it addresses the needs of the Population Program Wing of Planning Commission; Ministry of Health; Population Welfare Departments; and Departments of Health to procure contraceptives in accordance with the best international procurement practices. This key stakeholder group included Mr. Malik Amanat Rasul, Mr. Hamid Khalil, Mr. Muhammad Asghar, Mr. Syed Ilyas Haider, Mr. Ali Gohar Khan and Mr. Syed Asad Ali Naqvi of the Ministry of Population Welfare; Dr. Iqbal Ahmed Lehri and Dr. Hamid Afridi of Lady Health Worker Programme, Dr. Farooq Akhtar of MNCH Programme, Dr. Amir Maqbool and Mr. Rehman Shah of NACP, Mr. Malik Ahmad Khan of UNFPA, Mr. Farooq Azam and Mr. Inamullah Khan from DFID and AusAID supported Technical Resource Facility Project, Mr. Ghulam Rasul Dhotani and Mr. Muhammad Masood of Drug Control Authority/MOH, Dr. Muhammad Tanveer Alam from Central Drug Laboratory/MOH and Mr. Khalid Mahmood from USAID.

We also express our appreciation to Mr. Hafeez ur Rehman and Mr. Khalid Mahmood Lodhi, of the Public Procurement Regulatory Authority (PPRA) of Pakistan for their facilitation and guidance to ensure that the procurement manual is aligned and compliant with the Public Procurement Rules 2004 and Public Procurement Regulations 2008.

We appreciate the dedicated efforts of the USAID | DELIVER Washington team, including Shyam Lama and Jennifer Tuddenham, for their continued support during the process of developing the Contraceptive Procurement Manual.

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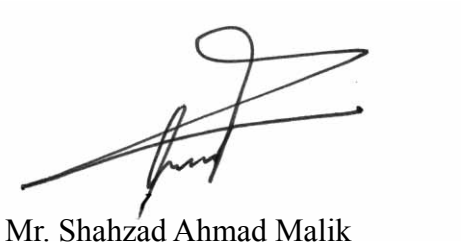
We gratefully acknowledge the support provided by Ms. Janet Paz-Castillo, Dr. Muhammad Ahmed Isa of USAID and Dr. Muhammad Tariq of USAID | DELIVER PROJECT in developing the Contraceptive Procurement Manual.

A list of all personnel who contributed to and supported the development of the Contraceptive Procurement Manual can be found in Appendix IX.



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Acknowledgment by Provincial Secretaries of Population Welfare Departments

The Contraceptive Procurement Manual is the first of its kind specifically focused on contraceptives. The manual is a complete guideline and reference document for all parties involved in procurement of contraceptives. The Contraceptive Procurement Manual is based upon best international procurement practices that promote transparency, accountability and efficiency in the procurement process. The endorsement of Ministry of Health, Public Procurement Regulatory Authority and Provincial Population Welfare Departments has rendered this document authentic.

USAID | DELIVER PROJECT held extensive consultations at both federal and provincial levels during the process of manual development. It is indeed commendable effort to ensure ownership from all levels of relevant stakeholders and it will certainly promote utilization of the manual. Streamlining procurement processes is one of the basic steps in ensuring availability of high quality contraceptive to everyone in Pakistan. We are thankful to USAID and USAID | DELIVER PROJECT for their financial and technical support respectively. The manual can be also adapted for non-contraceptive drugs and supplies. The support is indeed playing a critical role in ensuring contraceptive commodity security while keeping in mind the ongoing devolution under the 18th Amendment.

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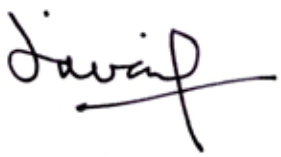

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Introduction

The Contraceptive Procurement Manual has been developed to provide the Ministry of Population Welfare and the Ministry of Health procurement personnel with the information and instructions needed to procure contraceptives of good quality on the international market to support Government of Pakistan Healthy Timing and Spacing of Pregnancy (HTSP) programme. The Contraceptive Procurement Manual incorporates best international procurement practices that help promote transparency, accountability and efficiency in the public sector procurement process. The Procurement Manual addresses the key phases of the procurement cycle, from procurement planning and issuing invitations to bid, to bid evaluation, supplier selection, contract award and management.

The primary audience for the Contraceptive Procurement Manual is procurement officers and other direct procurement staff who are assigned responsibility for procuring quality contraceptives. The Procurement Manual provides these personnel with step-by-step instructions for completing standard bidding documents, opening bids from suppliers, evaluating supplier bids and monitoring supplier performance. The manual also includes supplementary materials, such as information on pre-qualification and pre-shipment compliance programmes, which are designed to support procurement officers in effectively implementing public sector procurement of contraceptives.

The Contraceptive Procurement Manual also provides pertinent information for policymakers and mid-level decision makers who are not required to understand the detailed procedures of the procurement process, but should understand the overall procurement process for contraceptives and the role they can play to help ensure the procurement process is effectively implemented. It is recommended that this audience review Appendix V: Summary Guide for Policymakers, Directors and Managers.

The Contraceptive Procurement Manual also includes key national reference documents, such as the Public Procurement Rules 2004, Public Procurement Regulations 2008 and the Drugs (Labelling and Packing) Rules 1986, to ensure that procurement officers have access to original resource documents as they prepare for and conduct public sector procurement of contraceptives.

Users of the Contraceptive Procurement Manual are encouraged to thoroughly review the Manual in order to fully understand the breadth and scope of the information it contains so that they can be fully prepared to conduct effective public sector procurement of quality contraceptives for the people of Pakistan.

Acronyms

AQL	Acceptable Quality Level
AWB	Air Waybill
B/L	Bill of Lading
BD	Bidding Document
BDFC	Bidding Document Finalization Committee
BDS	Bid Data Sheet
BEC	Bid Evaluation Committee
BER	Bid Evaluation Report
BOS	Bid Opening Sheet
CDVAT	Customs Duty and Value Added Tax
CCIE	Controller of Import and Export
CF	Customs and Forwarding
CIF, CIP CFR, CPT	INCOTERMS
DC	Direct Contracting
DCA	Development Credit Agreement
DAF, DDP, DDU, DEQ, DES	INCOTERMS
DDS	Drug & Dietary Supplement
DoFP	Delegation of Financial Powers
EOI	Expression of Interest
EPI	Expanded Programme of Immunization
ETA	Estimated Time of Arrival
EU	European Union
EXW	Ex Works
FOB, FAS	INCOTERMS
FY	Fiscal Year
GCC	General Conditions of Contract
GOP	Government of Pakistan
GMDN	Global Medical Device Nomenclature
GMP	Good Manufacturing Practice
GPN	General Procurement Notice
HOPE	Heads of Procuring Entities
HTS	Harmonized Tariff System
Hz	Hertz

ICC	International Chamber of Commerce
ICT	International Competitive Tender
IFB	Invitation for Bid
IGM	Import General Manifests
INCOTERMS	International Commercial Terms
INN	International Non-proprietary Names
IS	International Shopping
ISO	International Standards Organization
ITB	Instructions to Bidder
IUD	Intra-uterine Device
L/C	Letter of Credit
L/D	Liquidated Damages
LC	Letter of Credit
LCA	Letter of Credit Authorization
LD	Line Directors
LIB	Limited International Bidding
MCH	Maternal & Child Health
MOH	Ministry of Health
MOPW	Ministry of Population and Welfare
MS	Member Secretary
MSR	Medical Surgical Requisites
NCB	National Competitive Bidding
NCT	National Competitive Tender
NOA	Notification of Award
NRA	National Regulatory Authority
NS	National Shopping
NCA	National Control Authority
OC	Oral Contraceptive
OTM	Open Tender Method
PAD	Project Appraisal Document
PEC	Proposal Evaluation Committee
PIP	Project Implementation Plan
PP	Procurement Plan
PPR	Public Procurement Regulations
PPRA	Public Procurement Regulatory Authority
PPS	Procurement Processing Schedule
QA	Quality Assurance

QC	Quality Control
QCBS	Quality Cost Based Selection
RFP	Request for Proposal
RFQ	Request for Quotation
RoRo	Roll on Roll off
SBD	Standard Bidding Documents
SC	Special Conditions
SBEF	Standard Bid Evaluation Form
SCC	Special Conditions of Contract
SMC	Social Marketing Company
SPN	Specific Procurement Notice
SRA	Stringent Regulatory Authority
SRFQ	Standard Request for Quotation
TIN	Taxpayer Identification Number
TN	Technical Note
TOR	Terms of Reference
UCP	Uniform Customs & Practice (for documentary credits)
UN	United Nations
UNDB	United Nations Development Business
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
UPS	Uninterruptible Power Supply
US	United States
VAT	Value Added Tax
WB	World Bank
WHO	World Health Organization

Procurement Basics

Procurement Basics include:

A. Principles of Good Public Sector Procurement
B. Principles of Competitive Bidding
C. Procurement Policy Guidelines
D. Procurement Methods - Goods (Contraceptives)
E. Rules and Tools for Procurement of Goods (Contraceptives)
F. Procurement Plans
G. Quality Assurance
H. INCOTERMS – for International Procurement
I. Letters of Credit and Other Payment Options
J. Specifications
K. Timeline for Procurement
L. Code of Ethics

A. Principles of Good Public Sector Procurement

The Government of Pakistan's Public Procurement Rules 2004 and Public Procurement Regulations 2008 are based on well-established and widely accepted principles of good public sector procurement:

Economy, Efficiency, Equality, Fairness, Transparency

Properly administered, open competition (competitive bidding) fulfills these requirements and is the backbone of good public sector procurement.

B. Principles of Competitive Bidding

1. **Suitable Package**
   Design bid requirements to attract the interest of both large and small foreign and domestic suppliers. Consider accepting partial bids, defining parts that must be bid together and those that can be bid alone.

2. **Early Warning**
   For National Competitive Bidding (NCB), allow bidders at least 15 days to submit offers. For International Competitive Bidding (ICB), allow bidders at least 30 days to submit offers.

3. **Non-discrimination**
   Invite bids from as many foreign and domestic suppliers as possible through open advertising in newspapers, trade journals and websites in accordance with alternate procurement methods as defined by the Public Procurement Regulatory Authority (PPRA).

4. **Accessibility**
   Allow wide access to competition by setting reasonable costs for bidding documents and securities; respond to all written questions and requests for additional information from each bidder as soon as possible; provide identical information to all other bidders without identifying the source of the inquiry.

5. **Neutrality**
   Base specifications on generic terms. Do not show preference for a specific brand or manufacturer in specifications; include the phrase "or equivalent" if a brand name, trademark or catalogue number must be used.

6. **Formality**
   Require that bids be in writing, signed and received in sealed envelopes before a stated date and hour.

7. **Confidentiality**
   Do not open bids until the assigned date and time. Restrict all bid information to authorized parties.

8. **Consistency**
   Evaluate all bids against the same criteria. Do not ask or permit a bidder to change the substance of his bid unless equal opportunity is given to all bidders within the competitive range.

9. **Objectivity**
   Determine if each bid is "substantially responsive" by checking for errors, correct signatures, inclusion of all required documents and adherence to basic bidding requirements. Select the most advantageous bid considering both the price and the evaluation criteria announced in the bidding documents.

10. **No Negotiation Before Award**
    Obtain the lowest responsible offer from each bidder through the competitive bidding process. Negotiate minor contractual adjustments after the winning bid has been selected.

C. Procurement Policy Guidelines

The Government of Pakistan has established clear Procurement Policy Guidelines which are intended to provide general guidance to personnel procuring contraceptives and services for health sector programmes. These guidelines include general principles such as evaluation of bids based on best overall value for money as opposed to lowest price, and a preference for Pakistani suppliers. The complete set of Procurement Policy Guidelines is located in Appendix I & II.

D. Procurement Methods - Goods (Contraceptives)

The Government of Pakistan requires purchasing entities to use the most appropriate method of procurement for a specific purpose. For the most part, conditions for use of specific methods are based on threshold values of future contracts. However, non-monetary issues, such as a limited number of suppliers worldwide, also play a role. The main methods for procurement of contraceptives are as follows:

1. **International Competitive Bidding (ICB)**
   ICB is an open or unrestricted bidding process that includes international sources. Bids are solicited by advertising an open invitation to suppliers around the world telling them about the opportunity to compete for a contract.

   Modules II-V of this manual explain ICB in detail.

2. **Pre-qualification of Bidders**
   The Government of Pakistan Procurement Policy Guidelines (Annexure 1) promote the prequalification of suppliers when purchasing drugs and medical supplies. Pre-qualification is a formal process whereby the opportunity to pre-qualify is widely advertised and applicants submit information on their technical, financial, performance history and manufacturing capacity for evaluation by the purchaser in advance of the procurement process. Bids are invited only from the pre-qualified firms rather than through open advertisement, but the rest of the procurement process is exactly the same as for ICB.

   Pre-qualification of potential bidders is described in Appendix VII.

3. **Open Competitive Bidding**
   Open Competitive Bidding is open, unrestricted, usually among national sources only. Bids are invited internationally through the PPRA website and through other internationally recognized procurement advertisement websites by which all suppliers are invited to participate in the bidding process. Open Competitive Bidding is the basis for GOP's Public Procurement Rules 2004 and Public Procurement Regulations 2008. One of the open competitive bidding procedures described in Rule 36 of the Public Procurement Rules 2004 may be adopted.

4. **Request for Quotation (RFQ)**
   The Government of Pakistan allows Requests for Quotation to be issued for procurement actions under Rs 100,000. In this method, quotations are requested and received from a limited number of suppliers; price and content are compared; award is made based on lowest evaluated cost.

5. **Direct Contracting (DC)**
   In Direct Contracting, price and terms are settled with one chosen supplier, without asking others for bids (e.g., without competition). The GOP limits the use of direct

contracting to rare circumstances, such as when there is only one producer/supplier in the world. Pre-approval is required.

6. Petty Purchases

This method is allowed by the GOP for goods with a value of less that Rs. 25,000. Petty purchases are exempted from the requirements of bidding or quotation of prices.

E. Rules and Tools for Procurement of Goods/Contraceptives

1. Rules for Procurement of Goods

a. Public Procurement Rules 2004

The Government of Pakistan has developed and adopted a set of modern procurement rules based on widely acknowledged principles of good public procurement practice. These rules are applicable to all procurement with public funds, except to the extent that the regulations conflict with an international obligation or agreement, then the provisions of that agreement prevail.

PPR 2004 covers the organization of public procurement, basic procurement rules and choice of procurement methods. Procurement detail is based on National Open Competitive Bidding. In addition, it describes the process for complaints and appeals. A copy of the Public Procurement Rules 2004 can be found in Appendix I.

b. Public Procurement Regulations 2008

The Public Procurement Regulations of 2008 build upon PPR 2004 and provide information on the procurement records to be kept, posting of contract awards on PPRA's website and Contract Award proforma forms. A copy of the Public Procurement Regulations 2008 can be found in Appendix II.

c. The Drugs (Labelling and Packing) Rules, 1986

The Drug (Labelling and Packing) Rules 1986 describe requirements for labelling and packing of drugs that are to be registered in Pakistan under the Drug Act 1976. A copy of the Drug Rules 1986 can be found in Appendix III.

2. Tools for Procurement of Contraceptives

The main "tools" applicable to procurement of goods are the Standard Bidding Documents used by GOP agencies and those offered by the World Bank.

a. GOP Standard Bidding Documents

GOP agencies such as MoPW and MoH have developed standard bidding documents for use in Open Competitive Bidding.

All relevant tools for procurement of contraceptives are part of this manual. This manual also includes relevant forms and information from the document

"Procurement Policies and Standard Operating Procedures: NHF Programmes for Ministry of Health and Ministry of Population and Welfare." Additional forms are also used in this manual.

F. Procurement Plan

The Government of Pakistan requires procuring entities to submit an annual (or annually updated, project-wise) procurement plan for approval before any procurement may take place. The procurement plan includes a broad description of the contraceptives to be purchased, a budget amount and source, a time period in which the contraceptives will be procured, and the method of procurement. Procurement planning is discussed further in Module I.

G. Quality Assurance

The quality of contraceptive products is an important component of an overall approach to quality of care within a family planning programmes. The consequences of poor quality product include lack of therapeutic effect as well as possible adverse health consequences. Poor quality products, or even the perception of poor quality, can also severely compromise the credibility of an otherwise successful family planning programme. For these reasons, assuring the quality of contraceptive products is critical.

For many, product quality assurance is often associated with a simple visual inspection of a product for defects, or running an analytical test. While these are certainly important components of quality assurance, the quality assurance process spans a much broader range of activities that run from the development of the product through to its use by the end user.

In discussing product quality, three terms – quality assurance, good manufacturing practices (GMP) and quality control - are often used interchangeably. While the activities complement and support one another, there are distinct differences between these terms.

Quality Assurance is generally understood to be the sum of all activities and responsibilities intended to ensure that products meet all their applicable quality specifications. A comprehensive quality assurance process also includes an oversight and auditing component to ensure that procedures and systems are suitable and, if necessary, to recommend appropriate changes.

Good Manufacturing Practices (GMPs) are the component of quality assurance that ensures products are consistently produced and controlled to the quality standards appropriate for their intended use and as required by the governing National Regulatory Authority. GMPs are intended to primarily reduce the risks inherent in production that cannot be prevented completely through the testing of final products.

Quality Control is the part of GMPs that is focused on product sampling, specification review and product testing. Quality control also includes the documentation and release

procedures to ensure that all necessary tests are carried out so that materials are not released for use, or products released for sale until their quality has been determined to be satisfactory.

The responsibility for ensuring product quality is shared among several parties: product developer, National Regulatory Authority, manufacturer, procurement agency, logistics system and end user. The role of the procurement agency is briefly described below.

The Procurement Agency is responsible for ensuring that only products of good quality are received in the health care system at the right time, in the right quantity and at reasonable cost. In accordance with national legislation, procurement should be limited to products approved by the national drug regulatory authority. The Procurement Unit has a significant impact on product quality by establishing well-defined contract specifications for the products it procures. Specifications should require certification that the manufacturer has complied with GMP, that the product is registered in the country where it is to be used and that it meets local regulatory requirements. In addition, contract specifications should describe the desired physical characteristics of the product as well as specify the pre-shipment inspection and test requirements against which the product will be evaluated before it ships from the manufacturer. The Procurement Agency may also help ensure only quality contraceptives are procured by limiting procurement to manufacturers whose contraceptives are prequalified by WHO or UNFPA or by procuring contraceptives that are manufactured and registered in countries with Stringent Regulatory Authorities.

The Contraceptive Procurement Manual contains information that supports the Procurement Agency's responsibilities in procuring quality contraceptives. The Technical Specifications contained in Appendix IV require manufacturers to provide: certification of registration, the drug manufacturing license number and certification of compliance with cGMPs. They also identify the physical requirements of the product and the physical tests to be conducted to confirm product acceptability. The Special Conditions of the Contract include clauses that grant the Procuring Agency the right to conduct pre-shipment and post-shipment inspections and tests to ensure the product complies with the stated requirements. For additional information on quality assurance, see Appendix VI: Product Quality Assurance. For additional information on Prequalification see Appendix VII: Pre-qualification. For additional information on pre-shipment inspection and testing see Appendix VIII: Pre-Shipment Compliance Programmes.

H. INCOTERMS – for International Procurement

INCOTERMS (such as EX Works, CIP and FOB) are incorporated into sales contracts world-wide to define the responsibilities of buyers and sellers and stipulate how costs and risks are to be divided. Thus buyers and sellers must always say which INCOTERM will apply when they discuss a price. If the price is agreed on an "EX Works" basis, it means the *buyer* will have to pay separately for freight and handling costs; if the *same price* is

agreed on a "CIP" basis, it means freight and handling costs are included in the price under discussion so the *seller* will pay them when the time comes.

INCOTERMS are published by the International Chamber of Commerce (ICC) and recognized by the United Nations for the purpose of clearly defining the most common terms used in international trade. Currently, there are thirteen INCOTERMS divided into four different groups:

> Group E (Departure): *The Seller makes the goods available to the Buyer at the Seller's own premises (EXW).*
>
> Group F (Shipment - carriage paid by Buyer): *The Seller delivers the goods to a carrier at a shipment point named by the Buyer, but does not pay for the carriage (FCA, FAS and FOB).*
>
> Group C (Shipment - carriage paid by Seller): *The Seller arranges and pays for the main carriage, but does not assume risks associated with bringing the goods to the country of destination (CFR, CIF, CPT, CIP).*
>
> Group D (Arrival): *The Seller bears all costs and risks associated with bringing the goods to the country of destination (DAF, DES, DEQ, DDU and DDP).*

INCOTERMS are updated regularly so purchase contracts must reference the version that applies. The information in this manual is based on INCOTERMS 2000.

Additional details along with a table summarizing the responsibilities of sellers and purchasers can be found in Annexure 2.

I. Letters of Credit and Other Payment Options

Letters of Credit are banking instruments commonly used in international trade; they have advantages for both the Buyer and the Seller:

- The Seller is assured he will receive prompt payment.
- The Buyer is assured he will be able to enforce contract conditions such as quality requirements and shipping dates.

Basic information on how a Letter of Credit works is located in Annexure 3. Other payment options and additional details about Letters of Credit are covered in Annexure 4 and in the ICC publication *Uniform Customs and Practice for Documentary Credits.* The Government of Pakistan, however, may prefer not to open an irrevocable Letter of Credit (L/C) to pay for contraceptives purchased under International Competitive bidding procedures.

J. Specifications

Detailed technical specifications are critical to successful procurement because they provide potential suppliers with an accurate and complete picture of what is required. They are written in the technical vocabulary of the relevant industry and precisely describe

characteristics and performance requirements of the goods to be purchased. They are "product neutral"; that is, they do not refer to brand names or catalogue numbers and describe requirements generically. If there are alternative sets of standard accessories to select from, the specifications clearly indicate choices. Under the bidding format used by both GOP and World Bank, the purchasing entity is responsible for providing technical specifications. Later, the formal specifications will become part of the contract between the supplier and the purchaser. Specifications are discussed further in Module I and in Module II. In addition, The Standard Bidding Documents for Procurement of Contraceptives, located at Appendix IV of this Manual, provides detailed guidance on contraceptive specifications.

K. Timeline for Procurement

Public sector procurement by ICB is not a fast process. Twelve months or more may be required for activities of the procurement office, evaluation committees, approval and time periods for manufacturing and shipping. Add to this an allowance of two to four months for normal government budgeting and planning (Operational Plans; Annual Procurement Plans) for a total of 14-18 months from the time a need is identified by an end user to the time goods are received, inspected and released for use.

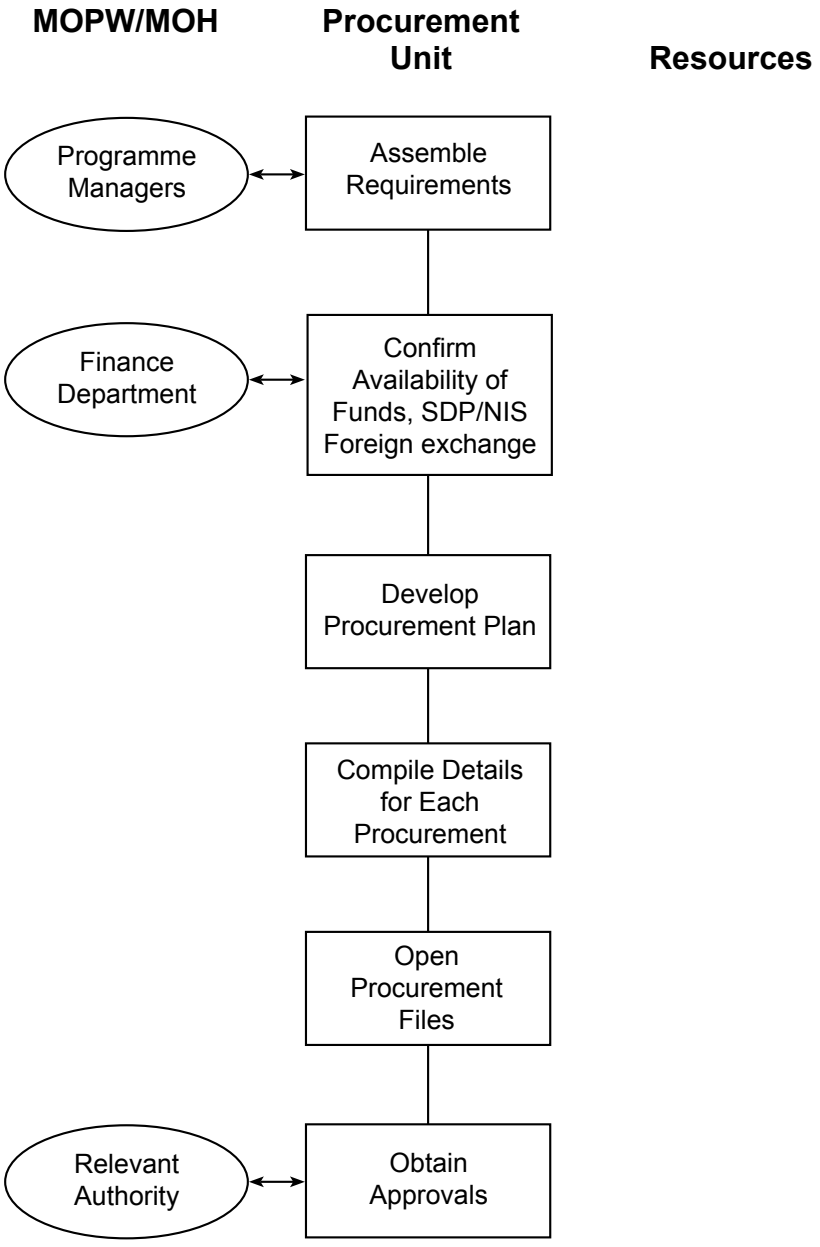
Of course, not all procurement takes 14-18 months. There are many variables at play, including – but certainly not limited to – procedures and approvals in force at different financial thresholds, supply issues such as marketplace shortages, technical issues such as availability of detailed specifications and quality assurance issues such as licensing of pharmaceutical products in Pakistan.

Procurement timelines are discussed further in Module I of this Manual.

L. Code of Ethics

The Government of Pakistan also promotes a business code of ethics to promote the professional behaviour of personnel engaged in procurement and contracting activities. This code is based upon the PPR 2004 Rule 2 Definition sub-rule (1)(f) Corrupt and Fraudulent Practices. A copy of the Code of Business Ethics and Integrity Pact can be found in Annexure 5.

Module I: Planning & Preparation



Module I includes:

A. Procurement Planning

B. Preparation for Procurement

A. Procurement Planning

Because of the long timeframe associated with competitive public sector procurement, realistic planning is very important. It is especially critical for health care commodities such as contraceptives (oral pills, injectables, condoms, etc.) because stock-outs of these items can cause unwanted pregnancies.

1. Budget Process and Operational Plan

Beginning in January each year, programme managers are asked to review their programme goals and activities for the coming fiscal year (July-June 30), consider probable resources (budget) and estimate contraceptives, equipment and services that will need to be purchased. These plans and estimates are submitted to the Ministry of Population Welfare (MOPW) and the Ministry of Health (MOH) where changes are sometimes made. The resulting Operational Plans and Budgets are consolidated and forwarded to the government for financial approval.

After the Annual Operational Plans have been refined and approved by the government, programme managers are responsible for communicating their approved requirements, usually in the form of a completed Procurement Requisition, to the appropriate procuring units, along with basic specifications and cost estimates within their approved budgets.

Two things are used to decide the amounts needed per year for procurement of contraceptives:

- An estimate of use based on population data and other factors. Trained specialists may be needed to help with this step.
- An account of how much stock is on hand and how much has been ordered but not yet delivered.

However, sometimes contraceptives may be purchased in quantities determined by budget availability, so re-supply calculations would not be relevant.

2. Procurement Plan

Obviously, every requirement cannot be processed at one time; so procurement plans are developed that include tentative, package-wise schedules for purchasing activities. An example appears as Annexure 6. As mentioned in the Basics Module of this Manual, procurement plans include a broad description of the contraceptives to be purchased, a budget amount and source, a time period in which the contraceptives will be procured and the method of procurement.

The GOP uses procurement plans to organize annual revenue expenditures for goods and services.

3. Confirm Availability of Funds

Before a specific procurement plan is developed for a contraceptive procurement, it is important to confirm with the appropriate finance section that adequate funds and, if needed, foreign exchange are available to support the procurement.

4. Process for Developing an Annual Procurement Plan

4.1 Gather Information

The assigned procurement unit should receive procurement information early in the year to allow for sufficient time to process and procure the requirement.

However, when procurement information is not provided in a timely manner, it may become necessary to directly contact the party responsible for generating the information to request it be provided by a specified deadline.

a. Send a letter to all users to submit their requirement for contraceptives for the next fiscal year by a specified deadline.

b. Send a reminder letter to users who do not respond within 45 days, with copies to the next higher level office stating the need to submit requirements by the specified deadline.

c. Prepare a list of users who have failed to submit their requirements by the final deadline.

d. Send a letter to the late people with a copy to the next higher level offices saying that the users who have failed to submit their requirements by the final deadline will not be included in the procurement plan for the following year, and no requirement will be accepted later.

4.2 Begin Filling Out the Procurement Plan

Using the sample format shown in Annexure 6, the procurement unit(s) should begin to fill out the Procurement Plan.

a. Describe the contraceptives and enter the unit and quantities required.

b. Show the estimated cost of the contraceptives and source of funds for each procurement.

c. Enter the procurement method (for example, ICB "International Competitive Bidding"). "Procurement Basics" of this manual contains detailed information on procurement methods. A chart showing the financial threshold limits for different types of procurement appears as Annexure 7.

d. Indicate the contract approving authority for each procurement (per financial thresholds).

4.3 Estimate Timeframes and Complete the Procurement Plan

In order to estimate a timeframe for any single procurement activity, it is necessary to understand the procurement steps involved, the level of approving authority required, time limits set by government regulation and basic marketplace issues for the contraceptives being procured.

- Annexure 8 shows an example timeline for procurement, assuming a high value contract and a high level approving authority.

a. Taking into account that procurement work will need to be sequenced (not all procurement is undertaken at the same time), insert indicative dates for: Advertising the Bid, Bid Opening, Bid Evaluation, Approval to Award, Notification of Award, Signing of Contract and Completion of Contract.

b. Add the total days and enter that number in the last column "Total Time (in days)".

B. Preparation for Procurement

1. Analyze Procurement Requirements

The Procurement Unit(s) must review requirements received from programs, which are often in the form of a procurement requisition, and analyze their needs in terms of:

- Type of contraceptive method
- Estimated quantity and cost of the contraceptives
- Potential sources of contraceptives
- Prior review requirements, etc.
- Type of supply available (i.e., after production, or off-the-shelf, or from wide range of market, etc.)
- Estimated lead time for delivery
- Previous frequency of purchase

At times it may be necessary for the Procurement Office to prepare a procurement requisition. For a sample procurement requisition form, see Annexure 9. For information on preparing a procurement requisition form, see Annexure 10.

2. Open Procurement File

The Procurement Unit will need to open one set of files for each procurement activity in the approved Procurement Plan. Each Procurement file must contain the appropriate procurement records as required by PPR 2004. Annexure 11 contains a list of records that can be considered for inclusion in the procurement file.

During the twelve to eighteen months it may take to complete the procurement process (from planning to delivery of goods), all pertinent records and documents should be placed in the appropriate file for easy reference. By the time the procurement action is complete, each file (or set of files) will contain a record of the entire procurement action

from the planning stage up to the completion of contractual liabilities. It is recommended that each procurement record contain the following files:

- Signed procurement requisition
- Product specifications
- Budget estimate
- Procurement plan and summary
- Bidders list
- Pre-qualification document
- Record of advertisement
- Bidding documents
- Bid security documentation
- Record of pre-bid conference
- Modifications to bidding documents
- Proposals from suppliers
- Record of bid opening
- Record of bid examination
- Bid review committee summary
- Award letter
- Performance guarantee documentation
- Signed contract
- Bidder notification
- Authorization for shipment
- Shipping documents
- Receiving report
- Miscellaneous correspondence

3. Procurement Records - Retention

The PPR 2004 requires procuring entities to preserve records and documents concerning their public procurement for a minimum period of five (5) years from the date the Supplier finally discharges its contractual obligations. In special cases, records may need to be kept for a longer period, for instance, in the case of development projects.

4. Summary Description of Planned Procurement

The procurement unit should write a "summary description" of each planned procurement in order to guide the development of bidding documents and specifications. An experienced procurement officer or a technical specialist should be assigned to gather any missing information. The summary description includes:

a. Description and function of the contraceptive in enough detail for development of a technical specification

b. Unit of measure (each, kgs/lbs, cycles, gross, tubes, etc.)

c. Quantity

d. Confirmed budget

e. Procurement method

f. Date needed

g. Final destination (within Pakistan, usually Central Warehouse)

h. Requesting programme manager or other entity and date of request

i. Shipping terms (CIP, EXW, etc.)

j. Payment terms (cash in advance, down payment, letter of credit, etc.)

k. Name and address of consignee

l. Project identification numbers

m. Procurement approval date

n. Special requirements for contract (including quality assurance testing)

o. Special marking requirements for shipping boxes

p. List of approvals required

q. Source of funds

r. Notes about special features of the goods or programmes they will be used for, or the overall market situation.

Newer procurement staff will need to seek help from more experienced officers about shipping and payment terms[1] that should be used for the procurement package.

The technical specification committee or other assigned technical experts may need to be consulted about the need for any special contract wording other than the technical specifications and schedule of requirements. In some cases, this information will not be available until the document development phase.

5. Development of Technical Specifications

Writing formal specifications requires a good understanding of the contraceptive to be purchased and working knowledge of the technical vocabulary used in the relevant industry. Thus, technical experts are often needed to help translate programme managers' approved requirements into technical specifications that will give potential suppliers an accurate and complete picture of what is required.

Early in the procurement process, technical consultants or other personnel may need to ask programme managers to provide more information or to make certain decisions about

[1] See Procurement Basics section of this manual.

their requirements. As soon as possible, information gathered from the end-users should be compiled into formal procurement specifications for use in the draft bidding documents.

Appendix IV contains sample technical specifications for contraceptives (oral contraceptives, injectables, IUDs, and condoms) that can be used for procurement.

6. Obtain Approvals

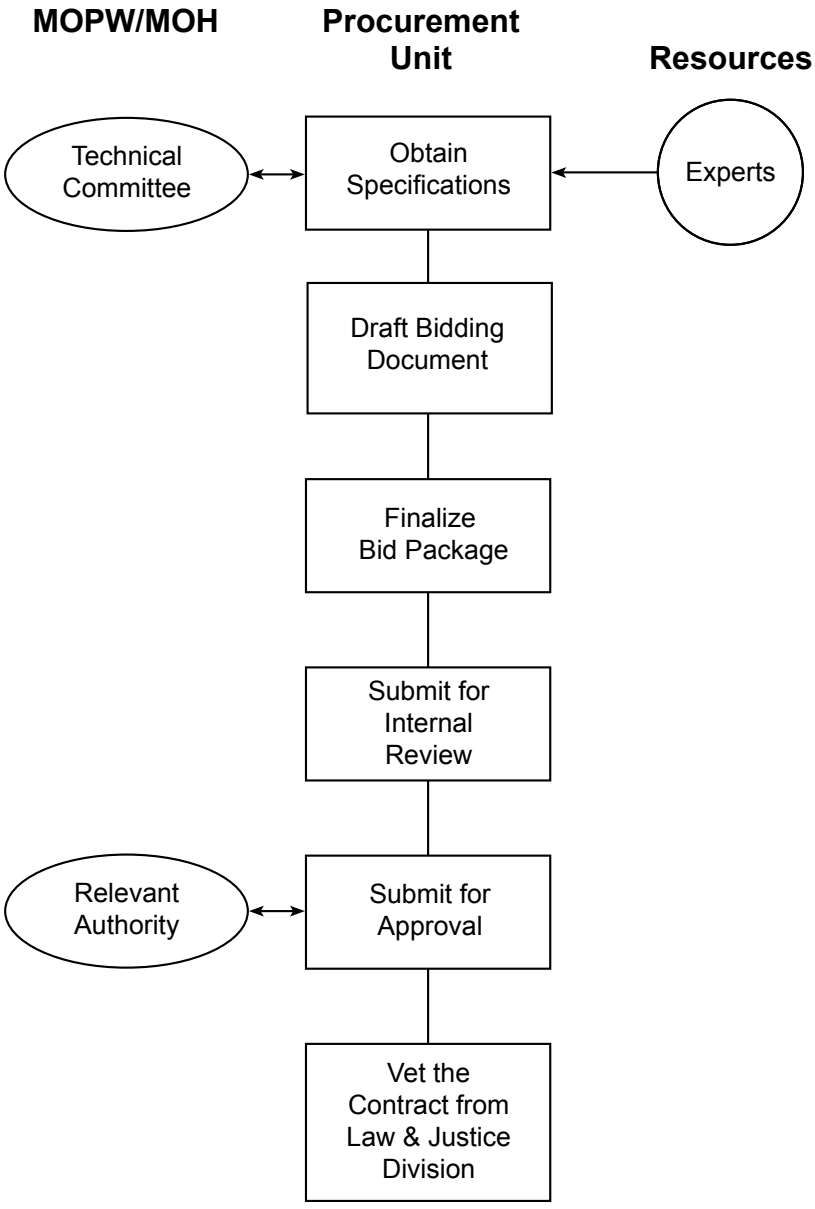
Approval by the Relevant Authority of the Procurement Plan constitutes administrative and financial approval for:

- Procurement of the goods included in the plan
- The method of procurement
- The time schedule for procurement as shown in the PP
- The office, cell, or other entity that will do the purchasing
- Prior approval requirements

7. Overview of Procurement Steps and Documents

Each procurement activity will follow a sequence of activity and requires specific documents according to the method of procurement employed. A Table of Procurement Steps and Documents has been prepared as a reference tool for new procurement staff in order to help them visualize the steps that may be required to conduct a high value contraceptive procurement. (See Annexure 12). It also provides a framework for what is to come in Modules II–V.

Module II: Standard Bidding Documents



This section includes:

A. Introduction
B. Description of Standard Bidding Documents
C. Process for Preparing Documents for Procurement

A. Introduction

In public procurement, detailed bidding documents are sold or otherwise provided to potential suppliers. These documents set all requirements about what is to be supplied, all rules and procedures for bidding, and announce the specific criteria that will be used for choosing a winning bid. Some sections also become part of the future contract between the supplier and the purchaser. Every aspect of these documents must be correct and complete. Under the Public Procurement Rules 2004 *nothing can be changed after bids are opened, even if a mistake is discovered.* Careful wording of the bidding documents is key to preventing problems during bidding, evaluation and contract performance.

This manual includes standard bidding documents which have been designed to support international procurement of contraceptives. They have been modified from the World Bank standard bidding documents, Procurement of Health Sector Goods - International Competitive Bidding (May 2004). These documents will be used for International Competitive Bidding procurement of contraceptives and condoms. For national procurement of contraceptives, however, the Ministry of Population Welfare and the Ministry of Health will continue to use bidding documents already developed for this purpose. The documents, Standard Bidding Documents - International Competitive Bidding - Procurement of Contraceptives, are an integral part of this Manual and are available in Appendix IV.

B. Description of Standard Bidding Documents

In the standard bidding documents, several sections must be used unchanged while other sections are to be filled in by the Purchaser. An overview of Standard Bidding Documents can be found at the beginning of Appendix IV. The Standard bidding documents include guidance notes and instructions to the procuring agency. Procuring agencies will delete the notes, instructions and unused options when they prepare documents for sale to potential bidders.

Each section of the standard bidding documents has a separate function:

1. **Invitation for Bids**
   Provides a copy of the advertisement or notification announcing the opportunity to bid along with relevant and essential information to help bidders decide whether or not to participate in the particular bid. It precedes sale of the Bidding Document and is provided with the documents for information only. The contents must be consistent with the Bid Data Sheet and Special Conditions of Contract. See Annexure 13 for a sample IFB form.

2. Instructions to Bidders (ITB)

The Instructions to Biddders provides information to help bidders prepare and submit their bids and explains rules and procedures with regard to:

a. Bid submission
b. Bid opening
c. Bid evaluation
d. Award of the contract
e. Definitions and warnings about fraud and corruption.

This section must be included in bidding documents "as is" without making any change to the wording whatsoever. (Information that is specific to the bid package is supplied through corresponding clauses in the "Bid Data Sheet" in the next section of the standard bidding document.) A sample Instructions to Bidders form with notes can be found in Appendix IV, Standard Bidding Documents - International Competitive Bidding.

3. Bid Data Sheet

The Bid Data Sheet provides information specific to the procurement action. The procuring agency uses this section to supplement and/or modify Instructions to Bidders. It includes, but is not limited to,:

a. Amount and type of bid security, if required
b. Directions for submitting bids, including markings and timeframe
c. Dates, times and other specific information about bid opening
d. Specific criteria that will be used to evaluate bids, including any factors other than price that will be applied
e. Criteria for eligibility of contraceptives and the particular documents required to establish eligibility and conformity to bidding documents
f. Criteria for eligibility and qualification of bidders and the particular documents required to establish bidder's eligibility and qualification
g. Specific information about awarding the contract. A sample Bid Data Sheet (BDS) can be found in Appendix IV Standard Bidding Documents - International Competitive Bidding.

4. Ineligible Bidders

Lists of firms that are excluded from bidding on specific contracts can be found on the Public Procurement Authority website at: www.ppra.org.pk. International agencies such as the World Bank, USAID, UNICEF, UNFPA, WHO and ADB also maintain lists of firms that are ineligible from bidding on their contracts due to violation of the fraud and corruption provisions. The Procurement Unit should not enter into any contract with such firms.

5. General Conditions of Contract (GCC)

Consists of widely used clauses that will apply to the future contract. This section must be included in the bidding documents "as is" without making any change to the wording whatsoever. *General Conditions* cover standard, normal contract issues such as:

a. Delivery
b. Payments
c. Warranty
d. Termination
e. *Force majeure*
f. Governing language
g. Notices

Changes and additions are made through Special Conditions of Contract (SCC). See Appendix IV, Standard Bidding Documents - International Competitive Bidding, for a sample General Conditions of Contract.

6. Special Conditions of Contract (SCC)

Provides clauses for the contract specific to the procurement action. The procuring agency uses this section to supplement and/or modify like-numbered clauses in *General Conditions of Contract.* Special Conditions apply to unique requirements of the procurement such as:

a. Requirement for immediate notification of air-shipments
b. Regulatory compliance issues
c. Pre-shipment inspection and testing (critical to condom procurement).
d. Any unacceptable trans-shipment points. See Appendix IV, Standard Bidding Documents - International Competitive Bidding, for a sample Special Conditions of Contract.

7. Technical Specifications (to be prepared by purchaser's technical expert)

Technical specifications provide a precise technical description of the goods to be supplied. The procuring agency inserts the specification (commonly prepared by a technical expert) into the Standard Bidding Documents.

Technical specifications are one of the most important parts of procurement. They constitute the benchmarks against which the Purchaser will verify the technical responsiveness of bids and subsequently evaluate the bids. The technical specifications must be in line with Rule 10 of PPR 2004. They must include a complete description of the product, presented in an industry-standard vocabulary and format, which includes, but is not limited to:

a. Technical and performance characteristics

b. Size, units, quantity and intended use
c. Packaging, packing, and marking
d. Regulatory requirements
e. Applicable standards and required certifications
f. Quality assurance criteria, including detailed tests required
g. Acceptance criteria
h. Detailed activities to be performed by the Supplier, if required
i. List of detailed functional guarantees covered by the Warranty

Note: Please review additional guidance note on Technical Specifications of contraceptives given in at Appendix IV, Standard Bidding Documents - International Competitive Bidding.

8. Schedule of Requirements

Lists the contraceptives and required delivery schedules.The procuring agency fills out a form provided in the standard bidding documents that specifies:

a. Procurement plan number
b. Named items required for purchase
c. Quantities
d. Delivery schedule
e. Special Notes

See Appendix IV, Standard Bidding Documents - International Competitive Bidding, for a sample Schedule of Requirements form.

9. Evaluation and Qualification Criteria

Announces criteria that will be used to determine the lowest evaluated bid, and the bidder's qualification requirements. Qualification criteria usually include, but are not limited to:

a. Financial capability in terms of average annual turnover during each of the past three years as evidenced by audited financial statements.
b. Experience and technical capacity demonstrated by the number of years manufacturing and/or selling the contraceptives to be supplied, completed contracts of similar nature with contact information for verification and bank references.
c. Licensing and registration by the Ministry of Health (where applicable). See Annexure 14 for detailed information about evaluation and qualification criteria for bidders.

10. Bid Submission

a. Bid Submission Form

To be completed and signed by the bidder.

- The signed Bid Submission form binds the successful bidder to conditions set out in the bidding documents and becomes a temporary contract when the award is notified.

See Appendix IV, Standard Bidding Documents - International Competitive Bidding, for a sample Bid Submission form.

b. Price Schedule

To be completed and signed by the bidder.

- Includes itemized charges for unit price of goods, domestic value added (if this applies), freight and insurance
- Separates foreign and domestic bidders in order to calculate a margin of preference for locally manufactured products (if this applies). See Appendix IV, Standard Bidding Documents - International Competitive Bidding, for sample price schedule forms for contraceptives manufactured inside and outside of Pakistan.

c. Manufacturer's Authorization Letter

To be completed and signed by the manufacturer of goods if the bidder is not the manufacturer.

- Authorizes named party (bidder) to submit a bid
- Confirms warranty obligation

See Appendix IV, Standard Bidding Documents - International Competitive Bidding, for a sample of Manufacturer's Authorization Letter.

d. Bid Security Form

To be filled in and signed by guarantor (bank) or used as example for document on its own letterhead.

- Guarantor's undertaking to pay specified amount if bidder receives an award but fails to go forward with a contract.

See Appendix IV, Standard Bidding Documents - International Competitive Bidding, for sample Bid Security forms.

e. Contract Agreement Form

To be signed by purchaser and winning bidder.

- Incorporates relevant sections of bid documents into binding contract.

- General Conditions of Contract
- Special Conditions of Contract
- Technical Specification and Schedule of Requirements
- Supplier's Bid and original Price Schedules
- Purchaser's Notification of Award
- Any other documents specified by Purchaser

See Appendix IV, Standard Bidding Documents - International Competitive Bidding, for a sample Contract Agreement form.

f. Performance Security Form

To be filled in and signed by guarantor (bank), or used as example for document on its own letterhead.

- Guarantor's undertaking to pay specified amount if awarded bidder defaults on contract.

See Appendix IV, Standard Bidding Documents - International Competitive Bidding, for a sample Performance Security form.

g. Bank Guarantee for Advance Payments

To be filled in and signed by guarantor (bank) or used as example for document on its own letterhead.

- Guarantor's undertaking to pay specified amount if Supplier uses advance payment for purposes other than toward delivery of the Goods.

See Appendix IV, Standard Bidding Documents - International Competitive Bidding, for a sample Bank Guarantee for Advance Payment form.

h. Certificate of Pharmaceutical Product

To be provided by manufacturer of pharmaceutical contraceptive.

- Establishes status of a pharmaceutical product moving in international commerce and of the applicant for the certificate with regard to certifications, licensing, marketing.
- Part of a scheme developed by World Health Organization to help combat sale and distribution of sub-standard and/or counterfeit pharmaceutical products.

See Appendix IV, Standard Bidding Documents - International Competitive Bidding, for a sample Certificate of Pharmaceutical product form.

C. Steps for Developing Draft Bidding Documents

All but three sections of the Standard Bidding Documents must be filled out with information specific to the procurement at hand. The sections that are to be filled out include:

a. Bid Data Sheet

b. Special Conditions of Contract

c. Evaluation and Qualification Criteria

d. Schedule of Requirements

e. Technical Specifications

Additionally, it will be necessary to construct an Invitation for Bids with information matching the Data Sheet and Special Conditions of Contract, once they have been developed.

Treatment of a particular topic must be consistent from section to section of the bidding documents and extreme care must be taken to avoid language that contradicts, overlaps or duplicates wording in another section.

The procurement unit will need to seek out information for the draft bidding documents and act as a coordination point for compiling the different sections. Some of the necessary information will be available from the approved Procurement Plan and preparations made at the early stages of procurement. Refer to the Summary Description of the planned procurement that was developed as described in section B.4 Module I for additional information.

1. Select and Study the Standard Bidding Documents

Procurement staff and managers should select the standard bidding document that best suits the requirements and the procurement method approved in the Procurement Plan, and study each section of the selected document thoroughly. This preparation will help to insure the bidding document draft is well prepared, consistent from section to section and covers all information needed for bid evaluation. In addition, it will impart a good understanding of how the procurement process is expected to proceed and the rules that must be followed.

The Procurement Unit must look for and identify any problems that might occur during bidding, evaluation and contract performance and try to design the bidding document clauses to prevent problems as much as possible.

Instead of working on the document sections in their established order, it is more efficient to start in the middle and work on several at the same time. The Technical Specifications and the Schedule of Requirements should be developed first, because they establish the "bones" of the procurement around which everything else will be built.

2. Obtain Technical Specifications

Detailed technical specifications should be written by qualified experts and provided to the Procurement Unit. Technical specifications include different things, depending on the type of product that is going to be purchased:

a. For pharmaceutical contraceptive procurement

- Chemical and pharmacological attributes
- Quality and safety issues
- Shelf life
- Presentation (primary packaging)
- Pre-shipment inspection (and possibly testing)
- Labelling

b. For condom procurement

- Dimensions
- Packaging
- Shelf life
- Pre-shipment inspection and testing
- Standards

2.1 If the specifications offered do not look appropriate based on the information above and the examples in Appendix IV, contact the responsible party, the technical consultant and/or the specification committee (if one exists) for clarification and any necessary revision.

2.2 Use the detailed specifications to guide development of all remaining bidding document components.

3. Prepare Schedule of Requirements

3.1 Review the Procurement Plan and Summary Description of planned procurement before working on the Schedule of Requirements.

3.2 Take the Schedule of Requirements section from the applicable set of standard bidding documents and look at it carefully.

3.3 Read the guidance notes and fill out the Schedule of Requirements as follows:

a. Procurement Plan: Insert a sequential number to identify the procurement plan.

b. Description: Write a short description of the contraceptives available in Appendix IV Standard Bidding Documents -- just enough to identify the product without confusion. (The technical specifications will provide a more detailed description.)

c. Quantity: Enter the total quantity that will be purchased under the contract. This is not the place to mention partial shipment amounts.

d. Delivery Schedule: Establish the date contraceptives are needed by the end-user then carefully calculate a "delivery date" taking into account the implications of INCOTERMS such as CIP that will apply to the procurement contract. In many cases, the contraceptives are considered delivered when they are handed over to the carrier, not when they reach their final destination. If this is the case, the calculation for "delivery date" should allow transit and clearing time in order for the contraceptives to arrive in Pakistan by the date needed.

The "delivery date" can be a specific month, day and year, or a number of weeks after a stated event, such as after confirmation of a letter of credit. This is the place to indicate if the product is to be delivered in partial shipments, and to outline the required schedule.

e. Mode of Shipment: Enter air, ocean, truck, etc.

f. Point of Delivery: For international procurement, the point of delivery will normally be determined by the INCOTERM, as noted above.

g. Special Notes: Additional information, explanations, or qualification may be added at the bottom of the form.

4. Begin Drafting the Bid Data Sheet

The function of Bid Data Sheets (BDS) is to modify and augment information and requirements printed in the Instructions to Bidders (ITB). Text in the ITB mentions the Data Sheet whenever specific information or requirements are needed to complete the instructions. All Data Sheet clauses are numbered to match corresponding, or "mother" clauses in the ITB.

4.1 Read and understand clause(s) in Instructions to Bidders corresponding to the required Data Sheet information. This is *very* important because the Data Sheet wording itself is not intuitive, that is, it is difficult to figure out what it means without referring to the "mother" clause. This will help to ensure time is not spent pursuing the wrong answers.

4.2 Consider whether ITB and standard data sheet clauses will adequately represent the procurement to be undertaken. Additional clauses may be included, so long as they do not contradict the standard instructions to bidders or the PPR 2004 rules.

4.3 Fill in all known information, for example, the name of the purchaser.

4.4 Make a list of information still needed to complete the Data Sheet (referenced by clause number).

4.5 Consider where/ how missing information might be obtained; for example, "programme decision", "earlier bidding document", "line director", "calculation", "consultant", "specification".

4.6 Pursue and coordinate necessary decisions, for example:

- Price of bidding documents
- Amounts of bid security
- Amount of performance guarantee
- Whether or not samples are required
- Date and time for pre-bid meeting, if required
- Bid opening date and time, bid validity requirement
- Whether or not bids will be accepted for less than the full quantity
- Whether the price should be quoted as fixed
- Whether or not domestic preference will be applied
- Whether evaluation will be on the basis of items or lots
- Bid currency and bid language

5. Specify Eligibility Criteria and Documents Required

Eligibility requirements, for the most part, are based on whether or not a firm has been debarred. Documentation requirements amount to the firm not being on the lists or debarred firms.

5.1 Determine and list on the Bid Data Sheet any criteria for eligibility in addition to those already mentioned in the ITB.

5.2 In the case of health sector documents, pursue appropriate wording for Data Sheet clauses 6.3 and 6.4 about procurement specific documentation of conformity with bidding documents and registration with the Pakistan Regulatory Authority.

5.3 Provide contact information for bidders to obtain additional information about requirements for registration of contraceptives.

6. Specify Evaluation Criteria and Documents Required

6.1 Determine criteria that will be used to evaluate and compare bids (in addition to what has already been mentioned in the ITB), and list it on the Bid Data Sheet. This will relate primarily to price adjustments and application of economic factors.

Examples include:

- Domestic preference
- Cross discounts
- Efficiency factors
- Possibility of early delivery

6.2 If criteria in addition to price are used, insert information for the bidder on how non-financial items will be evaluated.

6.3 In the examples above, the possibility of early delivery would also need to be mentioned in the Schedule of Requirements.

7. Specify Qualification Criteria and Documents Required for Evidence

Standard bidding documents for contraceptives procurement require four basic bidder qualifications:

a. The manufacturer must have adequate production capacity and experience.

b. The manufacturer must have verifiable technical capability.

c. The bidder must have verifiable business and financial stability.

d. The bidder must have a history of successful performance

It is up to the procuring agency to develop *specific criteria* that will be used in deciding whether or not a bidder is qualified for a contract award. For example, in the case of production capacity, the procuring agency would define exactly how much capacity it considers "adequate" based on quantity and delivery time requirements of the subject procurement and what documentary evidence the bidder should submit.

7.1 Determine for each of the four basic qualification criteria above, the specific criteria that will be required.

Guidance notes in the standard bidding documents provide assistance with designing appropriate qualification clauses. Qualification criteria for contraceptives include quality assurance elements.

7.2 Determine and list documentary evidence that bidders should submit in order to establish (or confirm) their qualifications.

Defining evidence in support of specific criteria is not as clear-cut as defining the requirement itself. The purchaser might ask the bidder for a sworn statement of its installed manufacturing capacity and peak and average production over the past three years. But at evaluation, other details and documents submitted with the bid will be used to corroborate the bidder's claims. The firm's financial information and audited financial statements, details of current commitments and contracts completed over the past several years and the bidder's explicit permission for the purchaser to contact business and banking references will all come into play.

See Annexure 47 for additional information to consider for the qualification of bidders.

8. Specify Any Addition Document Comprising the Bid

The ITB specifies what documents will comprise the bid, but also gives the procuring agency a chance to include more in this list through the respective Bid Data Sheet.

9. Bid Data Sheet Completion

Enter the products of Steps 4-8 above into the appropriate clauses of the Bid Data Sheet. Make sure all guidance notes and unused options are deleted. This is frequently overlooked and produces confusion about exactly what is required.

10. Begin Drafting Special Conditions of Contract (SCC)

Special Conditions of Contract (SCC) modify and augment information and requirements printed in the General Conditions of Contract. Whenever specific information or requirements are needed in the SCC to complete the contract conditions, this is noted in the text of the GCC in the same way the ITB and BDS were cross-referenced.

10.1 Read and understand the clause(s) in the appropriate version of General Conditions of Contract (GCC) corresponding to the Special Conditions requiring completion. This is very important because wording of the Special Conditions by themselves is not intuitive; that is, it is difficult to figure out what they mean without referring to the "mother" clauses. This will help to ensure time is not spent pursuing the wrong answers.

10.2 Consider whether the GCC and standard SCC clauses will adequately represent the procurement contract that is desired. Additional clauses may be included, so long as they do not contradict the standard GCC clauses or the prevailing procurement regulations and guidelines.

10.3 Fill in all known information. For example, nature of contraceptives to be supplied, purchaser's name, address, etc.

10.4 Make a list of information and decisions still needed to complete the SCC/PCC (referenced by clause number).

10.5 Consider possible sources where missing information might be obtained. For example, from the "Director General", "earlier bidding document", "line director", "consultant", "specification", "PPR 2004".

10.6 Pursue and coordinate necessary decisions. For example:

- Documents that will become part of the contract
- Packing, marking, documentation requirements
- Method and conditions of payment
- Inspections and tests required

10.7 Make a list of resources and capabilities that will be needed during execution of the contract. For example, inspection agents, insurance surveyors, testing facilities, customs clearing services, banking and letter of credit facilities, etc.

10.8 Gather information about local import practices, procedures, and requirements. For example:

- Import licensing
- Dockside sampling programme
- Currency exchange regulations
- Customs tariff and taxes

- Pro-forma invoice
- Product registration
- Documentation
- Letter of Credit (L/C) procedures
- Confirm that L/C capability has already been arranged with a registered bank in Pakistan.

10.9 Take steps to correct deficiencies in resources and capabilities that will be needed during procurement and contract performance. In particular, pay attention to international services such as testing laboratories and pre-shipment inspection services. In a few cases, research on local practices and capabilities will reveal problems. For example, inspection agents may need to be appointed and/or letter of credit arrangements may need to be set-up in order to service the future contract. The Procurement Unit should set any required processes in motion as soon as possible, so that delays will not occur when the services are needed.

11. Enter Specifics for Certification of Goods Clause

Pharmaceutical contraceptives require registration with the Ministry of Health, Government of Pakistan, (where required), and contracts generally cannot become effective until this has been accomplished.

SCC 6.1 asks for details of registration. SCC 6.2 provides wording in the case contraceptives have already been registered or registration is not required. SCC 6.3 provides a limit on how much time can pass before the contract will be considered null and void.

Note

The procuring entity cannot sign the contract until registration of the contraceptives, under the Drug act of 1976, has been completed. It is critically important for the procurement office to be aware of registration status and monitor progress because Drug Regulatory procedures can delay contract signing and the contraceptive delivery date.

12. Enter Specifics for Inspections and Tests Clauses

12.1 Note inspections and tests that will be applicable to the contract. Options include:

a. Pre-shipment compliance by supplier

b. Pre-shipment compliance by purchaser

c. General dockside sampling and inspection (government import programme)

d. Acceptance testing in Pakistan

12.1 Specify inspections and/or tests not otherwise mentioned in the standard documents, and provide a cross reference to corresponding requirements in Schedule of Requirements and Technical Specifications.

Pre-shipment inspection and sampling is conducted at the manufacturer's facility and testing, if required, is done at an independent laboratory before shipment. An independent laboratory meeting all the international standards prescribed by WHO for testing of contraceptives should be selected. This is known as a "pre-shipment compliance programme". It may include all or part of the following:

a. Documentary review
b. Inspection at the manufacturer's facility
c. Sampling
d. Testing at an independent laboratory

Pre-shipment compliance programmes insure that safe, good quality products reach the end users and eliminate the time and trouble of involved in returning contraceptives, and waiting for another shipment when sub-standard or incorrect contraceptives are detected.

In cases where timely receipt of contraceptives is critical to programme operations, pre-shipment compliance programmes are very important. See Appendix VII for information on pre-shipment compliance programmes.

13. Enter Specifics for Packing, Marking and Package Documents Clauses

List requirements that are in addition to the GCC text, and provide a cross-reference to corresponding requirements in Schedule of Requirements and Technical Specifications. For example, you may want certain information printed on the outside of the packing boxes in order to facilitate warehousing and distribution, or there may be a requirement to pack contraceptives so they remain below a certain temperature, as is the case with vaccines.

14. Enter Specifics for Shipping and Other Documents to be Furnished by Supplier

Determine and list shipping documents that will be required. Possibilities include:

a. Commercial invoice
b. Air waybill
c. Clean on-board Bill of Lading*
d. Packing list
e. Certificate of analysis

Any other documents that may be required for shipping and customs clearance for specific items should be identified by the procurement unit and provided by the manufacturer.

* Particular care should be taken with specifying the Clean on-board Bill of Lading

Note

If the Letter of Credit is going to require the seller to present the original, negotiable Bill of Lading to a specific bank for payment, then the contract clause about shipping documents should not require the seller to send it (the original, negotiable bill of lading) to the purchaser with other advance shipping documents. (The purchaser receives the Bill of Lading from the commercial bank after the supplier is paid. See information on Letters of Credit in Basics Module.)

14.1 Determine and list documents that will be required to establish the product's conformity to basic specifications. (Required items should also be mentioned in the corresponding specification.) For example:

a. Certificate of analysis
b. Quality assurance records

14.2 State the number of originals and number of copies required for each document.

15. Complete the Remaining SCC Clauses

Make sure all required entries have been made and that treatment of each issue in Special Conditions is consistent with wording in the corresponding Bid Data Sheet, Schedule of Requirements and Technical Specification.

16. Construct the Invitation for Bids

Using information in the completed Bid Data Sheet, Special Conditions of Contract, Specifications and Schedule of Requirements, prepare the Invitation for Bids by following the format and directions provided in the Standard Bidding Document. See Annexure 13 for sample Invitation to Bid form.

17. Compile Draft Bidding Documents Package

The bidding documents must be compiled in accordance with Rule - 23 of PPR 2004. Some of the sections/information that are part of the bidding document include:

a. Invitation for Bid
b. Instructions to Bidders
c. Bid Data Sheet
d. General Conditions of Contract
e. Special Conditions of Contract
f. Schedule of Requirements
g. Technical Specifications

h. Eligibility for Provision of Goods

i. Forms to be filled out, referenced, or used by the bidder (Bid Form, Price Sheet, Bid Security, etc.)

j. Apply page numbering and construct a Table of Contents and a Title Page

18. Prepare Bidding Documents Fact Sheet

A Fact Sheet for the Bidding Documents should contain an "at-a-glance" overview of important information about the package, including:

a. Short description of the contraceptives

b. Estimated cost and quantity of the contraceptives

c. Procurement method

d. If prior review is, or is not, required

e. Requesting agency (end user)

See Annexure 15 for a sample Fact Sheet on Bidding Document form.

19. Prepare Prospective Bidders' List

The Procurement Unit will develop a list of suppliers who may be able to provide the required contraceptives. This list can be used for ICB (international competitive bidding) when direct invitations will be issued instead of, or in addition to, advertising.

Sources for potential suppliers include:

a. Responders to General Procurement Notice

b. Prior marketing knowledge

c. National and international registers and publications

d. International non-governmental organizations

e. Foreign embassies

f. Chambers of commerce

g. Donors and UN agencies

h. Firms previously enlisted by GOP

i. Firms pre-qualified by an earlier formal process

20. Submit Draft Bidding Documents for Internal Review

Send draft copies of the bid package and fact sheet to the responsible parties within MOPW and MOH, who should:

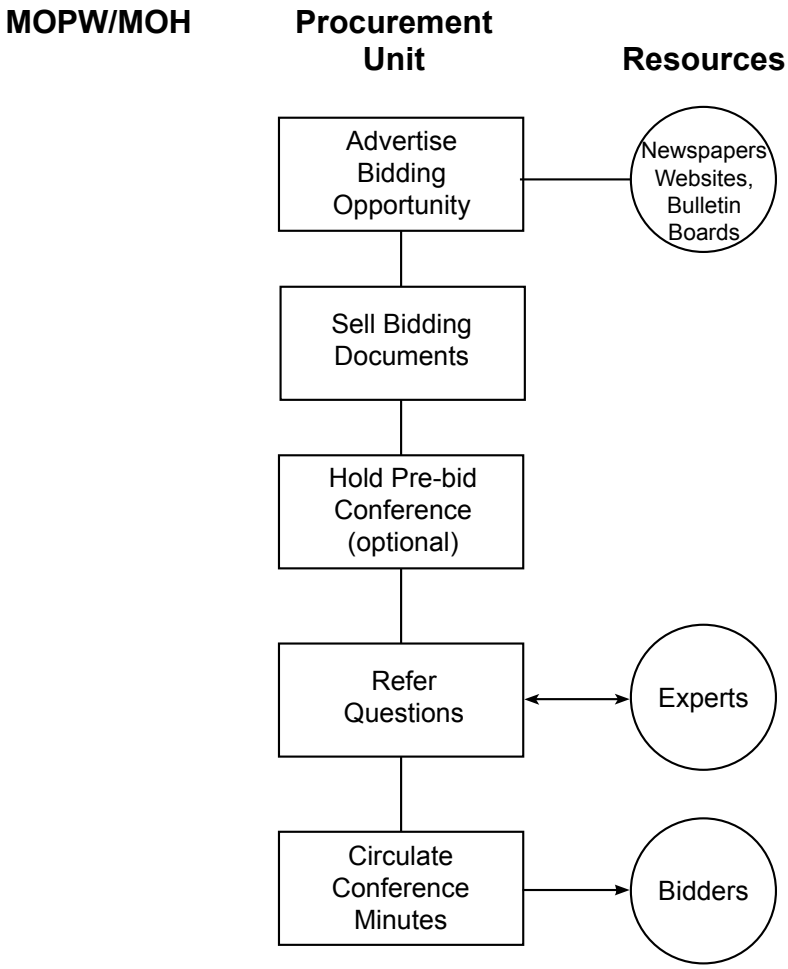
a. Check the draft against the Procurement Plan

b. Verify authenticity of the requirement of the contraceptives

c. Investigate any other relevant factors

d. Check to make sure the technical specifications are accurate and have appropriate detail
e. Make sure any evaluation criteria in addition to price are clearly stated and appropriate for programme needs
f. Endorse (approve) the draft Bidding Documents for onward disposal with or without revision.

Module III: Invitation and Receipt of Bids



This section includes:

A. Steps for Inviting Bids

B. Pre-bid Conference

A. Steps For Inviting Bids

1. Advertise the Opportunity to Participate in Bidding

As soon as the Relevant Authority approves the draft Bidding Document, the Procurement Unit must advertise the opportunity for bidding. That is, it must extend a public invitation to participate in the competition for a contract to all interested firms and parties. This is one of the essential elements of "open competition".

The Public Procurement Rules 2004 require that procurements of over Rs 100,000 and up to Rs 2 million be posted on the Public Procurement Regulatory Authority's website at: www.ppra.org.pk.

For procurements anticipated to be above Rs 2 million the PPR 2004 requires that the procurement opportunity be published in print media or newspapers with wide circulation, as well as on the PPRA, concerned ministries and any international advertisement websites. Print media advertisements should be placed in at least two daily national newspapers, one in Urdu and one in English. See Annexure 16 for a sample format for advertisement of an international competitive bid.

1.1 Prepare a version of the Invitation for Bids that is suitable for newspaper and periodical publication.

1.2 Using the format identified in Annexure 16, prepare a version of the Invitation for Bids that is suitable for website publication. Submit the advertisement following instructions and using facilities provided on the appropriate website.

1.3 Place advertisements in the national daily newspaper and official gazette, as required. It is important for both the newspaper and website advertisements to be published at the same time. Otherwise, potential bidders may be justified in seeking an extension to the period for the submission of their bids, thus delaying procurement.

1.4 For international competitive procurement, also place advertisements in appropriate international journals, publications and websites, such as dgMarket. The World Bank's Health Sector Bidding Documents suggest *SCRIP – World Pharmaceutical News.*

1.5 Post notices at the procurement office and on official or public notice boards.

1.6 Inform all the Chambers of Commerce in Pakistan.

1.7 In the case of ICB, send notices to foreign embassies and trade missions present in Pakistan.

2. Prepare Bidding Document Sets and a Document Register

Documents must be ready for issue or sale to interested parties at the time of the appearance of the advertisement.

2.1 Determine the number of bidding document sets that should be produced for sale based on:

- **a.** The type of goods to be purchased.
- **b.** The approximate number of prospective bidders (for example, a small number for contraceptives).
- **c.** The source of goods (national or international).
- **d.** Previous sale of bidding documents for similar goods.

2.2 Determine the number of bidding document sets needed for official Ministry purposes.

2.3 Prepare sets (copies) of the bidding documents.

2.4 Set up a register to record all bidding document sets that are prepared for the package. Number the documents so that each set can be accounted for when the bidding process is complete.

3. Prepare Systems for Safeguarding Bids, Cash and Securities

3.1 Arrange a secure location to hold Bids unopened until the stated day and time of bid opening; for example, a locked cabinet.

3.2 Set up a system for handling funds collected from prospective bidders for the cost of the bidding documents.

3.3 Set up a system for safeguarding securities after bids have been opened.

4. Set Up Procedure for Transmitting Bidding Documents to Prospective Bidders Outside of Pakistan

4.1 Select methods – mail, courier, express document service.

4.2 Arrange capacity for paying postage or courier fees.

5. Availability of Bidding Documents to Bidders

5.1 Bidding documents for international procurement should be made available by the Procurement Unit. Price should be minimal and only reflect the cost of printing and providing the Bidding Documents.

5.2 Use the register mentioned in 2.4 above to record the name, address and document number of each purchaser so they can be informed about any pre-bid conferences, amendments to the documents, or other official business.

5.3 Use the register mentioned in 2.4 above to record the name, address and document number of the sets forwarded at no cost to official sources.

5.4 Provide receipts to Bidders with name, address date and time.

B. Pre-Bid Conference (Optional)

Pre-bid conferences of prospective suppliers are held for international and important local procurements when it is thought necessary. At a pre-bid conference, potential bidders' questions are answered and minutes are recorded and sent to each recipient of the original bidding documents in sufficient time before the deadline for receipt of bids to enable bidders to take appropriate actions.

In a competitive situation, these conferences can become difficult to control. So it is very important to set a firm agenda and make an advance plan for managing the flow of questions and answers. Bidding documents may need to be amended as a result of questions and issues that are brought up by registered participants. Procedural errors during the conference, or in writing or distributing the minutes can result in official protests by competing bidders. Any protest is likely to delay the procurement.

1. **Arrange the Pre-Bid Conference**
   Any pre-bid conference should take place well ahead of the bid opening date. The concerned director should determine a convenient place and time for the conference. The room must be large enough to hold at least:
   - **a.** Two representatives from every intending and prospective bidder.
   - **b.** All officers and directors who had a major role in developing or approving the draft bidding documents. These individuals may be organized into a Bidding Document Finalization Committee.
   - **c.** Appropriate Procurement Unit staff and their Director(s).

2. **Notify Prospective Bidders**
   Give a notice about the conference to the prospective bidders at the time they purchase the Bidding Documents. All prospective bidders up through the last one to purchase them before the pre-bid conference should receive this notice.

3. **Hold the Pre-Bid Conference**

3.1 Register participants and generate an attendance list, including titles and contact information. *Limit attendance to parties who have purchased bidding documents.*

3.2 Record the minutes following the sample given in Annexure 17.

3.3 Refer questions and concerns that cannot be answered at the conference to technical experts immediately. A sample reference letter is shown as Annexure 18.

3.4 Forward replies (per 3.3 above) to registered participants and all registered bidders as soon as they are received using the sample format shown in Annexure 19.

3.5 If necessary, extend the bid submission period and/or amend the bidding documents based on the answer to the questions asked during the pre-bid conference.

4. Circulate the Minutes and/or Outcome of Pre-bid Conference

Note

All parties who have *purchased bidding documents must receive exactly the same information.*

4.1 Send the minutes and other related information to all prospective bidders, including those who purchased Bidding Documents *after* the pre-bid conference.

4.2 Send a copy of the conference minutes to the end-user office.

5. Extend the Bid Submission Deadline if Necessary

5.1 Notify prospective bidders if the bid submission deadline is extended. Use the sample format of notification shown in Annexure 20.

5.2 Place notification of the extension on the website(s) (dgMarket) where the original Invitation for Bids first appeared.

5.3 If there is sufficient time, also place the notification in appropriate newspapers and publications.

6. Receiving and Managing Bids

6.1 Bids must be held unopened until the stated day and time of bid opening.

6.2 Bid envelopes should be stamped with the date and time they are received.

6.3 Except for questions and answers in writing to/from procurement, no one associated with the procurement is permitted to communicate with bidders regarding the bid from the time the advertisement appears until after an award has been made.

This section includes:

A. Introduction
B. Bid Evaluation Format
C. Steps for Bid Opening
D. Steps for Verifying Bid Securities
E. Steps for Organizing the Bid Evaluation Process (SBEF Tables 1-4)
F. Steps for Examining Bids (SBEF Table 5)
G. Steps for Financial Evaluation (SBEF Tables 6-11)
H. Steps for Qualifying Lowest Evaluated Bidder
I. Assembling the Contract
J. Recommending for Award
K. GOP Approvals and Authorization
L. Extension of Bid Validity
M. Redressal of Grievances

A. Introduction

For MOPW and MOH contracts, bid opening, evaluation and selection of a winning bidder is governed by the Public Procurement Rules 2004, Clause 30, which states:

1. All bids shall be evaluated in accordance with the evaluation criteria and other terms and conditions set forth in the prescribed bidding documents. Save as provided for in sub-clause (iv) of clause (c) of rule 36, no evaluation criteria shall be used for evaluation of bids that had not been specified in the bidding documents.
2. For the purpose of the comparison of bids quoted in different currencies, the price shall be converted into a single currency specified in the bidding documents, as notified by the State Bank of Pakistan that day.
3. A bid opened in accordance with the prescribed procedure shall be subject to only those rules, regulations and policies that are in force at the time of issue of notice for invitation to bid.

B. Bid Evaluation Format (*how*)

PPR 2004 does not define a specific evaluation procedure or offer a step-by-step format for selecting a winning bid, but requires a bid comparison sheet, a recommendation for award and an evaluation report.

The Standard Bid Evaluation Forms (SBEF) of the World Bank conform with the provisions of the Public Procurement Regulatory Authority (PPRA) rules and may be adopted for use and guidance in evaluating bids. A Table of Contents for these evaluation forms is shown in Annexure 21. What follows below should be regarded as background information for procurement officers but step-by-step guidance for individuals who have been formally assigned to an evaluation committee.

Standard Bid Evaluation Form (SBEF) Documents

The SBEF provides tables and forms designed to help procuring entities examine and evaluate each bid submission and arrive at a winning bid based on a fair application of the rules, procedures and requirements set down in the bidding documents. This Module (IV) will use the SBEF to explain the bid opening, evaluation and award stages for contraceptive procurement.

C. Steps for Bid Opening

Bids must be opened publicly for both local and international procurements at the time mentioned in the bidding documents. Bidders may attend the opening but it is not required.

1. Organize the Bid Opening (Officers of Procuring Agency)

1.1 At least 7 (seven) days ahead of bid opening, notify members of the Bid Opening Committee (BOC) using the format shown in Annexure 22.

1.2 Arrange the place for bid opening as specified in the bidding documents. It should be well lighted, should be large enough to accomodate at least two persons from each bidding firm and should have audio facilities, if required.

1.3 Hold all bids unopened and secure until the date and hour designated in the bidding documents.

2. Record Bid Submissions (Officers of Procuring Agency)

As bids arrive:

2.1 Provide receipts

2.2 Record the bidder name and the submission date. (Bids received after the exact deadline will not be opened.)

3. Hold Bid Opening (Bid Opening Committee)

On the date and at the time and place specified on the bidding documents:

3.1 Admit Participants:

- **a.** Authorized bidders
- **b.** Others directly involved with the subject procurement; for example, consultants hired for the purpose.

3.2 Require each attendee to register his/her presence in an Attendance Register provided for that purpose, including:

- **a.** Name, address
- **b.** Company, manufacturer, representing
- **c.** Organizational affiliation (if not bidder)
- **d.** Signature

e. The Attendance Register should be countersigned by a member of BOC

3.3 Open all bids received before the deadline one at a time and read aloud:

a. Bidder's name and local agent's name, if different

b. Bidder's City/State or Province/Country

c. Withdrawal or modifications, if any

d. Currency(ies) of the bid

e. Bid price

f. Discounts, if any

g. Presence or absence of any required bid security

3.4 Record samples received. Record any samples received with the bid on a Record of Samples Received form. See Annexure 23 for a sample form for recording samples received.

3.5 Do not open bids received after the deadline for receipt of bids. Such bids must be returned unopened to the bidder.

4. Record and Distribute Details (Bid Opening Committee)

4.1 As each bid is being read out, complete a Bid Opening Checklist similar to Annexure 24. No bid that was received on time may be eliminated at this stage, even if something appears to be missing or incorrect.

4.2 Record the details of the bid on a Bid Opening Sheet (BOS), or Record of Bid Opening similar to Annexure 25.

4.4 Require all members of the BOC and the bidders or their representatives who attend the bid opening to sign the BOS/Record of Bid Opening upon completion of the opening.

The above steps provide a summary of the key activities to be performed in bid opening. For additional detailed guidance on opening bids, see Annexure 26.

Note

After the public bid opening and report, there should be no further contact with bidders until the winner is identified and notified. No circumstances justify meetings or conversations between the purchaser and bidders during the evaluation process.

D. Steps for Verifying Bid Securities

Bid securities in a fixed amount ranging from approximately 1 percent to 2 percent of the estimated price are submitted with bids from both local and international bidders. The bidding documents will state which form(s) of bid security can be accepted.

Generally accepted securities include:

- Pay Order
- Bank Draft
- Bank Guarantee
- Letters of Credit

No cash money is allowed.

1. Safeguard and Record Bid Securities

1.1 Segregate bid securities soon after the bids are opened.

1.2 Hold bid securities in a locked, secure location until a contract has been awarded.

1.3 Record each bid security in the register set up for this purpose.

2. Confirm Bid Securities

The validity of all bid securities should be confirmed within 15 days after the bid opening.

2.1 Confirm bid securities issued by banks within Pakistan (local issuing banks) by going to the bank and actually speaking with a bank officer.

2.2 Confirm bid securities issued by banks or other institutions outside of Pakistan by e-mail, fax, telegram, telex, letter, etc. The sample request letter shown in Annexure 27 may be used.

2.3 Confirm bid securities issued by banks outside of Pakistan but having a correspondent bank within Pakistan, by visiting the correspondent bank and speaking with a bank officer.

E. Steps for Organizing the Evaluation Process (SBEF Tables 1-4)

1. Fill out SBEF Tables 1-3

1.1 Fill out SBEF Table 1, Identification (see Annexure 28). It requires very basic information about the subject procurement package, most of which can be found in the approved Procurement Plan, including the original cost estimate. The remaining information is located in the Bidding document.

1.2 Fill out SBEF Table 2, Bidding Process (see Annexure 29) with basic information about the bidding process, which includes publication dates, title of bidding documents, and amendment dates.

1.3 Fill out SBEF Table 3, Bid Submission and Opening (see Annexure 30) with information about the bid submission and opening which includes deadline and opening dates, bid validity period and number of bids received.

2. Check Copies and Secure Bid Originals

2.1 Compare each copy of each bid with its original and correct accordingly, if necessary.

2.2 Confirm that signatures on each original are present as required.

2.3 Keep originals in a safe location and use copies for evaluation work.

3. Complete the Bid Opening Checklist for Each Bid

3.1 Enter any incomplete information. For example, descriptions and currencies announced at bid opening may need to be elaborated further.

3.2 Verify information recorded at bid opening.

4. Complete SBEF Table 4 – Bid Prices as Read Out (See Annexure 31)
The information required for this table may be found on the bid opening checklists and bid opening record.

F. Steps for Examining Bids (SBEF Table 5)

The purpose of the Examination outlined in SBEF Table 5 (see Annexure 32) is to identify and reject bids that are incomplete, invalid, or substantially non-responsive to the bidding documents. Only bids that pass this phase can go on for financial evaluation and comparison with other bids.

1. Review Original Bidding Documents
In order to evaluate a bid, we must know *what* to evaluate and that comes from the original bidding documents.

1.1 Thoroughly review the original Bidding Document issued for the procurement.

1.2 Particularly note entries in the Bid Data Sheet and Special Conditions of Contract as well as the Schedule of Requirements to get an understanding of what each bid should be agreeing to or offering.

2. Review Preliminary Examination Form (SBEF Table 5)
SBEF Table 5 is a summary record showing how each bid for a goods contract is substantially responsive or substantially non-responsive to the bidding documents. It includes columns for recording the bidder's name, verification information, eligibility information, bid security information, completeness of bid, substantial responsiveness, and acceptance for detailed examination. Additional columns can be added as necessary. In most cases, they will be required for responsiveness to technical specifications and commercial conditions.

Each column of Table 5 (except Bidder's Name) will need to have at least one supplementary schedule or checklist in order to record details of each bid's responsiveness or non-responsiveness in that category. These supplementary schedules must reflect the exact requirements, terms and conditions of the original bidding documents. The

following sections discuss how to complete the supplementary schedules for SBEF Table 5 columns. Also, a case study has been developed to illustrate how these supplementary schedules and SBEF Tables 5 through 11 are completed. See Annexure 53 for the sample case study).

3. Refer Bids for Technical Evaluation

Soon after bids are opened, a technical expert or a Technical Evaluation Sub-Committee should be assigned to the task of examining the bids for technical content. Although it is not listed on the Table 5 headings, the technical evaluation is a critical part of determining a bid's responsiveness to the requirements and whether or not it can proceed to the next stage – financial evaluation and comparison.

3.1 Examine each bid for modifications, exceptions and interlineations (notations written between the lines of the original bidding documents) regarding:

- **a.** Compliance with technical specifications provided in the bidding documents.
- **b.** Compliance with general and Special Conditions of Contract included in bidding documents that are related to technical specifications. For example, contract requirements for pre-shipment inspection, sampling and testing.

3.2 List and cross-reference deviations from bidding documents and indicate whether or not they are acceptable or unacceptable along with the reasons.

3.3 For each bid record and document findings regarding compliance with technical specifications. See Annexure 33 for a sample Technical Evaluation Sub-schedule for recording technical evaluation findings. A list of the actual technical specifications must be incorporated into this schedule.

3.4 If bidders are required to submit samples for inspection and/or testing, it is the procurement unit's responsibility to facilitate arrangements for any necessary testing to be done at a qualified government testing laboratory or at a pre-qualified independent testing laboratory and obtain written reports.

Note on Testing

Testing is sometimes restricted to samples from several prospective suppliers with the lowest substantially responsive bids, but may also be reserved for bids from new or previously unreliable suppliers. In this case, testing would be delayed until the financial evaluation is complete.

Testing samples submitted with bids are not appropriate for health sector goods, such as contraceptives, pharmaceuticals, and vaccines, because this will not assure the quality of *a product batch to be produced in the future.*

3.5 Summarize findings and provide overall comments on the technical evaluation. A sample summary table for recording information about the technical evaluation may be found in Annexure 34. A list of the actual technical specifications must be incorporated into this schedule.

4. Undertake Verification Exercise: Table 5 – column b

Annexure 35 is a sample checklist for column b of Table 5 for examining details of verification issues. Real bidding documents will include additional issues that must be examined during the verification exercise. The BEC should:

4.1 Review bidding documents for items to be checked in this category and prepare a checklist.

4.2 Examine all bids and note deficiencies that, if accepted, would provide unfair advantages to the bidder. *Significant judgment* must be used. For example, simple omissions or mistakes resulting from human error should not be grounds for rejection of the bid. However, the validity of the bid itself, for example, its signature, must not be in question.

4.3 Do not consider any information contained in a bid submission that was not specifically requested in the bidding document.

5. Assess Eligibility of Bidder: Table 5 - column c

Annexure 36 is a sample checklist for examining details of eligibility issues. Real bidding documents will include additional issues that should be addressed during the eligibility examination. The BEC should:

5.1 Review bidding documents for items to be checked in this category and prepare a list.

5.2 Check the PPRA website for a list of debarred firms.

5.3 Confirm the eligibility of each bidder and the goods offered.

a. If pre-qualification has taken place, only bids from pre-qualified bidders can be considered.

b. A bidder may be disqualified if it has been placed on a debarment list by GOP.

6. Examine for Conformance of Bid Security: Table 5 – column d

Annexure 37 is a sample checklist for column d of SBEF Table 5 for examining details of bid security. Real bidding documents will include additional issues that should be addressed during the bid security examination.

6.1 Review bidding documents for items to be checked in this category and prepare a list.

6.2 Make sure that all bid securities conform to the requirement stated in Instructions to Bidders (ITB).

7. Examine Bids for Completeness: Table 5 – column e

Annexure 38 is a sample checklist for column e of SBEF Table 5 for recording details about the completeness of the bid. Real bidding documents will include additional issues that should be addressed during the bid completeness examination.

7.1 Review bidding documents for items to be checked in this category and prepare a list.

7.2 Review the bids and note if any are incomplete or deviate from the original documents.

a. Unless the bidding documents have specifically allowed bidders to quote for only select items or for only partial quantities of an item, bids not offering all of the required items (both type and quantity) will ordinarily be considered non-responsive. This decision requires *significant judgment.*

b. Changes or additions to the bidding document by the bidder are usually treated as deviations, but may be acceptable if they are simply corrective, editorial or explanatory. This also requires *significant judgment.*

8. Examine Bids for Commercial Responsiveness (sub-schedule for Table 5 - column f)

Annexure 39 is a sample sub-schedule for column f of SBEF Table 5 for examining details of commercial responsiveness. Real bidding documents may include additional issues that should be addressed during the commercial responsiveness examination. Deviations that are specified in the bidding documents (Instructions to Bidders section) as requiring rejection of the bid must be listed.

9. Obtain and Review Technical Evaluation Report

The technical expert, or committee, indicates whether or not the bid is technically acceptable (see Annexures 33 and 34). The bid committee notes this determination in its evaluation report.

10. Identify Substantially Responsive Bids: Table 5 - column f

10.1 Review the technical evaluation report and the findings from the other sub-schedule evaluations of SBEF Table 5 and determine whether or not each bid is substantially responsive to the requirements terms and conditions stated in the Bidding documents.

Note

This step requires significant judgment and extreme care. The procuring entity may regard a bid as responsive, even if it contains minor deviations.

Bids that are determined to be "not substantially responsive" cannot be considered further (in other words, they will not be evaluated on the basis of price). Major deviations from the commercial requirements (8 above) and technical specifications

(9 above) are a basis for the rejection of bids. Bidders are *not* allowed to correct or withdraw material deviations or reservations after bids have been opened.

Definitions

A bid is considered *substantially responsive* when it is presented in the required manner and appears to include all required information, samples, statements, securities, signatures, forms and supporting documentation, and contains no material deviations from or reservations to the terms, conditions, and specifications in the bidding documents.

A *material deviation* is a significant and unacceptable difference from the requirements stated in the bidding documents. As a general rule, major (or material) deviations are those that, if accepted, would not fulfill the purposes for which the bid is requested, or would prevent a fair comparison with bids that are properly compliant with the bidding documents.

A material (or major) deviation affects the price, quantity, quality, or delivery of the goods as required in the bid documents, or limits the responsibilities, duties, or liabilities of the bidder, or any rights of the purchaser.

However, bids that offer deviations may be considered substantially responsive—at least as to the issue of fairness—if the deviations can be assigned a monetary value that would be added as a penalty during the financial evaluation process and if such deviations would be acceptable in the eventual contract.

11. Accept Bids for Financial Examination (Table 5 - column g)

11.1 List each bid and indicate whether it will be accepted for detailed evaluation, based on the results of their examination. If a bid fails acceptance, the reasons must be clearly explained in footnotes or in an attachment. The Table 5 column number and schedule where the bid fails to meet requirements should be indicated.

This determination requires *significant judgment* and extreme care. Bids that are judged "substantially non-responsive" must be rejected without further consideration.

G. Steps for Financial Evaluation (SBEF Table 6-11)

For each bid that survives the examination stage, the BEC must arrive at an "evaluated cost". SBEF Tables 6-11 help insure a fair comparison among all the offers. Subject to post-qualification, the bid with the lowest "evaluated cost," *but not necessarily the lowest submitted price*, must be chosen for award.

The "evaluated cost" is not necessarily the submitted price; it takes corrections, discounts and other factors into consideration and gives them a value. Bidding documents must list factors to be considered, in addition to price, and describe the manner in which they will be applied.

1. Calculate Corrections and Unconditional Discounts (SBEF Table 6)

The BEC should use Table 6 (see Annexure 40) to incorporate corrections and unconditional discounts in the calculation for an "evaluated cost".

1.1 Corrections for Errors: For each bid, multiply the unit price by the quantity. If the answer does not match the totals or sub-totals mentioned in the bid, the difference should be entered as a plus or minus in column "d". In other words, the stated unit price prevails. If there is a discrepancy between words and figures, the amount in words prevails. Corrections are considered binding on the bidder. Unusual or large corrections that could affect the comparative ranking of bids should be explained in footnotes.

1.2 Corrections for Provisional Sums: Sometimes the bidding documents ask bidders to include provisional sums for contingencies. These sums are the same for all bids and they must be entered as a minus in column "e" to allow for a proper comparison of bids.

1.3 Modifications and Unconditional Discounts: Bidders are allowed to modify their bids prior to opening. These modifications may include either increases or discounts to the bid amounts that reflect last minute business decisions. Enter any modification or unconditional discount that is not reflected in the read-out bid price into columns "g" and "h".

1.4 Corrected/Discounted Bid Price(s): Table 6, column "i" shows how to calculate this important figure. Cross discounts are not included yet. They are calculated after all other evaluation steps are completed.

2. Fill out Exchange Rate (SBEF Table 7) (See Annexure 41)

2.1 Check the original bidding documents (ITB) and enter the currency specified for the purpose of comparison.

2.2 Attach a copy of the exchange rates provided by the specified authority or publication (usually, The State Bank of Pakistan) to Table 7.

The corrected/discounted bid prices will be converted to a common evaluation currency in the next step.

3. Calculate Currency Conversion - Multiple Currencies (SBEF Table 8) (See Annexure 42)

This table is used for goods. It calculates a total bid price in the specified evaluation currency using the exchange rate(s) in Table 7.

4. Calculate Additions, Adjustments and Priced Deviations (SBEF Table 10, see Annexure 43)

4.1 Additions: Amounts from Table 8 must be entered in column "b". Omissions to the bid are then compensated for in column "c" by adding an estimated price. For example, tools which are not included with the price of a vehicle. Where items missing in some bids are present in others, an average of quoted prices can be used. External sources, such as published price lists, freight tariff schedules, etc., are also appropriate. The addition should be expressed in the evaluation currency.

4.2 Adjustments: The original bidding documents may specify performance or service factors (costs or savings) that will be taken into account in the evaluation by assigning cash value to a non-cash factor. If these factors are going to be used, they will be explained in the Data Sheet section of bidding documents. The methods used to evaluate these factors must be consistent with the Data Sheet provisions and must be described in the evaluation report. The value of adjustments are expressed in the evaluation currency and shown in column "d".

4.3 Priced Deviations: Bids with minor deviations may be considered substantially responsive if a monetary cost or penalty is assigned to the bid for the purpose of bid comparison. Vague statements by the bidder, such as "we wish to discuss changes in the delivery schedule" should be ignored. However, an explicit statement by a bidder, such as "we wish to extend the delivery date by 30 days", should be treated as a deviation. In this case, the time difference can be assigned a monetary value based on the rate of liquidated damages specified in the bidding documents. The penalty amount should be entered in column e in the evaluation currency.

4.4 Total Price: Enter the new total price in column "f ". Table 10 calculates a sum of columns "b", "c", "d", and "e". Extra care should be taken in the calculation if any amounts in column "d" (or "e") should be subtracted rather than added.

5. Calculate Domestic Preference for Goods (SBEF Table 11) (See See Annexure 44)

Table 11 calculates the margin of preference for offers of goods produced in Pakistan and applies it to the bid price of foreign offers, if goods from within Pakistan are not the lowest offer. The Instructions to Bidders and Bid Data Sheet will indicate if a domestic preference is allowed.

5.1 Divide bids into three groups (Group A, Group B and Group C).

Group A: Bids exclusively offering goods manufactured in Pakistan, if labour, raw materials and components amount to more than 30% of the Ex-works price of the product offered.

Group B: All other bids offering goods from within Pakistan.

Group C: Bids offering goods from abroad that have already been imported or that will be directly imported (quoted on CIP basis).

5.2 Review the Bid Form and Price Schedules that were submitted by the bidders. Each bid should be checked to make sure the Bidder filled out the correct price schedule for his group classification (A, B or C).

5.3 Determine the lowest bid in each group (A, B and C) by comparing all bids in the group against each other, using the amount calculated in Table10, column f.

5.4 Compare the lowest bids from each group (A, B and C) and if a bid from Group A or Group B is the lowest, it should be selected for the award.

5.5 If the lowest bid is from Group C (foreign), compare it with the lowest bid from Group A after adding a premium to the bid price of the group C bid following the instructions below.

Column c – Total Price: Enter the amounts calculated in Table 10, column f.

Column d – Exclusions for Preference: Enter sums of the amounts calculated in Table 10, columns d and e plus other costs incurred within the Purchaser's country. Footnotes should be written to explain the significant components of column d.

Column e – Revised Total: Enter the amount of column c, less column d.

Column f – Prevailing Tariff (%): Ignore this column. It is no longer used.

Column g – Domestic Preference (%): Enter 15%.

Column h – Preference Price: For Group C (foreign) bids, multiply the percentage in column g times the revised total in column e. For Group A bids, enter 0 in column h. At this stage, Group B bids should no longer be considered.

Column i – Total Comparison Price: Add the amount in column h to the amount in column c for each bid and enter the total in column i. This is the price that will be used for establishing the lowest "evaluated" bid.

5.6 If the Group A bid is now the lowest, it should be selected for the award. If not, the lowest bid from Group C should be selected.

6. Assemble Summary Ranking of Financial Evaluation

As a matter of clarity and convenience, a summary ranking of the financial evaluation of technically responsive bids should be developed listing the bidders and their total bid price. A revised schedule may be needed if domestic preference or cross discounts change the ranking. See Annexure 45 for a sample Ranking Worksheet for Financial Evaluation.

7. Apply Any Cross-Discounts

These are conditional discounts offered when more than one contract or lot could be awarded to the same bidder. The BEC must select the best combination of awards on the basis of least overall cost of the total contract package. Bid evaluation in such cases can be complicated, with many variations.

The Cross Discount worksheet (see Annexure 46) shows an example of basic information and calculations needed to determine whether it would be less expensive to purchase a group of bid packages individually from each of the lowest evaluated bidders, or as a group of bid packages from one bidder who offers a discount applied to the total.

Column a (first line): Enter name of bidder offering a Conditional Discount.

Column b (first line): List the bid packages that would be discounted by bidder in column a if all packages in the group were awarded to him. Include the package number and the price without discount.

Column c (first line): Enter the discount offered by the bidder (usually a percentage).

Column d: Apply the discount in column c to each bid package price noted in column b to find a discounted price for each bid package. Next, calculate the sum of the discounted bid package prices and enter that amount on the first line of column d.

Column e: Starting on the second line, list the lowest evaluated bidder for each separate bid package in column a, the corresponding bid package number in column b and the bid prices in column e. Next, calculate the sum of the lowest evaluated bid prices and enter the total on the first line of column e.

Column f: Indicate the lower of column d and e; include remarks.

Include a copy of the Cross Discount worksheet in the bid evaluation report if cross discounts were offered.

H. Steps for Qualifying Lowest Evaluated Bidder

If pre-qualification was conducted, the bidder whose bid is the "lowest evaluated" should receive the award unless:

- Bidder's qualifications have since materially deteriorated.

The Purchaser must satisfy itself fully on following accounts.

- Examine the updated information submitted by the "lowest evaluated" bidder and determine if it still meets the original pre-qualification criteria. Seek clarification or updates from the bidder as required.
- Where the "lowest evaluated" bidder is still qualified, include this information in the evaluation report.

If pre-qualification was not conducted, the lowest evaluated bidder must be post-qualified using the requirements mentioned in the bidding documents.

1. Develop a Bidder's Qualification Worksheet

1.1 In order to facilitate the qualification process, develop a bidder's qualification worksheet based on qualification criteria announced in the bidding documents. Annexure 47 is an example of bidder qualification criteria that can be used for a worksheet.

1.2 Also see Module II, Section 7 of this Manual.

2. Examine Documents and Statements

2.1 Examine the documents and statements provided by bidder with regard to qualification criteria announced in the bidding documents.

2.2 Record findings on the worksheet.

3. Check References

3.1 Contact reference persons and institutions provided by the bidder to verify statements and obtain information on past performance and financial standing.

4. Determine Qualification Status

4.1 Decide if the lowest evaluated bidder satisfies all qualification criteria.

4.2 If the lowest evaluated bidder fails post-qualification, its bid should be rejected, and the next ranked bidder should then be subject to the same post-qualification examination. If successful, this bidder should receive the award. If not, the process continues.

4.3 If a bidder fails post-qualification, the justification must be clearly explained and documented in attachments to the bid evaluation report. A history of poor performance may be considered adequate justification.

I. Assembling the Contract

The contract is important because once it is signed it becomes a legally binding document between the purchaser and the seller that identifies:

- Product specifications
- Delivery requirements
- Performance obligations of both parties
- Legal recourse for the parties involved in case of lack of performance or disputes.

Contract preparation for international competitive bidding occurs during the process of developing the bidding documents when product specifications, delivery requirements, general and special contract conditions and QA requirements specific to the contraceptive are assembled. While this can be a complex preparation process, the bidding documents provide the bidder with all the pertinent contract information and requirements so that

come contract award time, the contract is basically in place and the winning bidder has only to sign the contract agreement form.

The documents that typically are included in the contract include:

i) The Form of Contract
ii) The Bid Form and the Price Schedule submitted by the Bidder
iii) The Schedule of Requirements (offered by the Bidder and accepted by the Purchaser)
iv) The Technical Specifications (offered by the Bidder and accepted by the Purchaser)
v) The General Conditions of Contract
vi) The Special Conditions of Contract (duly filled in)
vii) The Performance Security submitted by the Bidder

The purchaser should review the assembled contract documents to ensure that key requirements and contract provisions from the following categories are included in the contract as needed:

- Product requirements
- Delivery requirements
- Certification requirements
- Inspection and testing rights
- Payment terms
- Special QA conditions appropriate to the commodity
- Funder requirements (if required)
- Warranty clauses
- Termination clauses
- Remedy clauses

J. Recommending for Award

1. Prepare a Bid Evaluation Report

1.1 The purchasing entity prepares a bid evaluation report that provides information documenting the bid opening process, the preliminary bid examination, the technical evaluation and the financial evaluation. See Annexure 48 for a sample Bid Evaluation Report. Even when only one bid is submitted, the bidding process may be considered valid, if the bid was satisfactorily advertised and prices are reasonable in comparison to market values.

1.2 Attach notes of explanation for any extraordinary factors such as prices higher than estimated, lower than expected, only one bid submitted, etc.

1.3 Recommend the lowest evaluated, qualified bidder for award.

1.4 Sign the evaluation report – that is, each member must sign with their name and designation clearly stated.

1.5 In the event of disagreement with the recommendation by any member of the BEC, a member may provide a note of dissent describing his/her reasons in detail.

2. Submit Report to GOP Approving Authority

2.1 Submit the evaluation report along with recommendations for award and any note of dissent, if any, to the approving authority. See Annexure 49 for a sample Request for Evaluation Report form and Annexure 50 for a Contract Award Approval form.

K. GOP Approvals and Authorization

1. The award recommendation must be formally approved by the appropriate GOP approving authority.

2. After reviewing the Bid Evaluation Report Summary and confirming that the bid evaluation process has been properly adhered to and the award recommendation is consistent with a fair and equitable bid evaluation process as documented by the Bid Evaluation Report Summary, the GOP approving authority is bound to approve the award recommendation in a prompt manner.

By promptly approving award recommendations that are based on a fair and equitable bid evaluation process, the approving authority helps to:

a. Increase the confidence of bidders in the GOP procurement process which encourages bidders to compete for GOP contracts, thereby increasing competition which can lead to reduced product prices.

b. Reduce the number of protests filed by Bidders when they believe that the approving authority made an arbitrary decision not based on the bid evaluation process and that, as a result, their bid did not receive fair and equal consideration as required by the PPR 2004.

c. Ensure the contract is awarded to the manufacturer in a timely manner to support the product delivery schedule.

3. If the Approving authority determines that the bid evaluation process as documented by the Bid Evaluation Report summary was not conducted in a fair and equitable manner, then it may:

a. Seek any clarification required from the Bid Evaluation Committee.

b. Reject the Recommendation, clearly documenting in writing the reasons for the rejection, and request a re-evaluation.

c. Reject the Recommendations, clearly documenting in writing the reasons for the rejection, and issue instructions to reprocess the procurement in accordance with the PPR 2004.

4. The decision of the approving authority will be communicated to the Procuring Agency through the same route in which the request for approval was initially submitted.
5. After the approval has been received by the Procuring Agency, the Notification of Award (NOA) for the procurement contract must be issued within 15 days provided that no complaint or appeal is pending under the PPRA against the bidder.
6. For contract awards greater that Rs 50 million, the Purchaser must complete Contract Award Proforma I (see Annexure 51) and Contract Award Proforma II (see Annexure 52) for posting on the PPRA website.

L. Extending Bid Validity (if necessary)

If justified by exceptional circumstances, a Procuring Entity may request a bidder to extend the validity period of its bid. Bidders are not obliged to agree to such requests. However, if a bidder agrees, it must be in writing and confirm the new date for the expiry of bids that has been requested by the procuring entity. If the bidder has submitted bid security, the bid security must be extended as well.

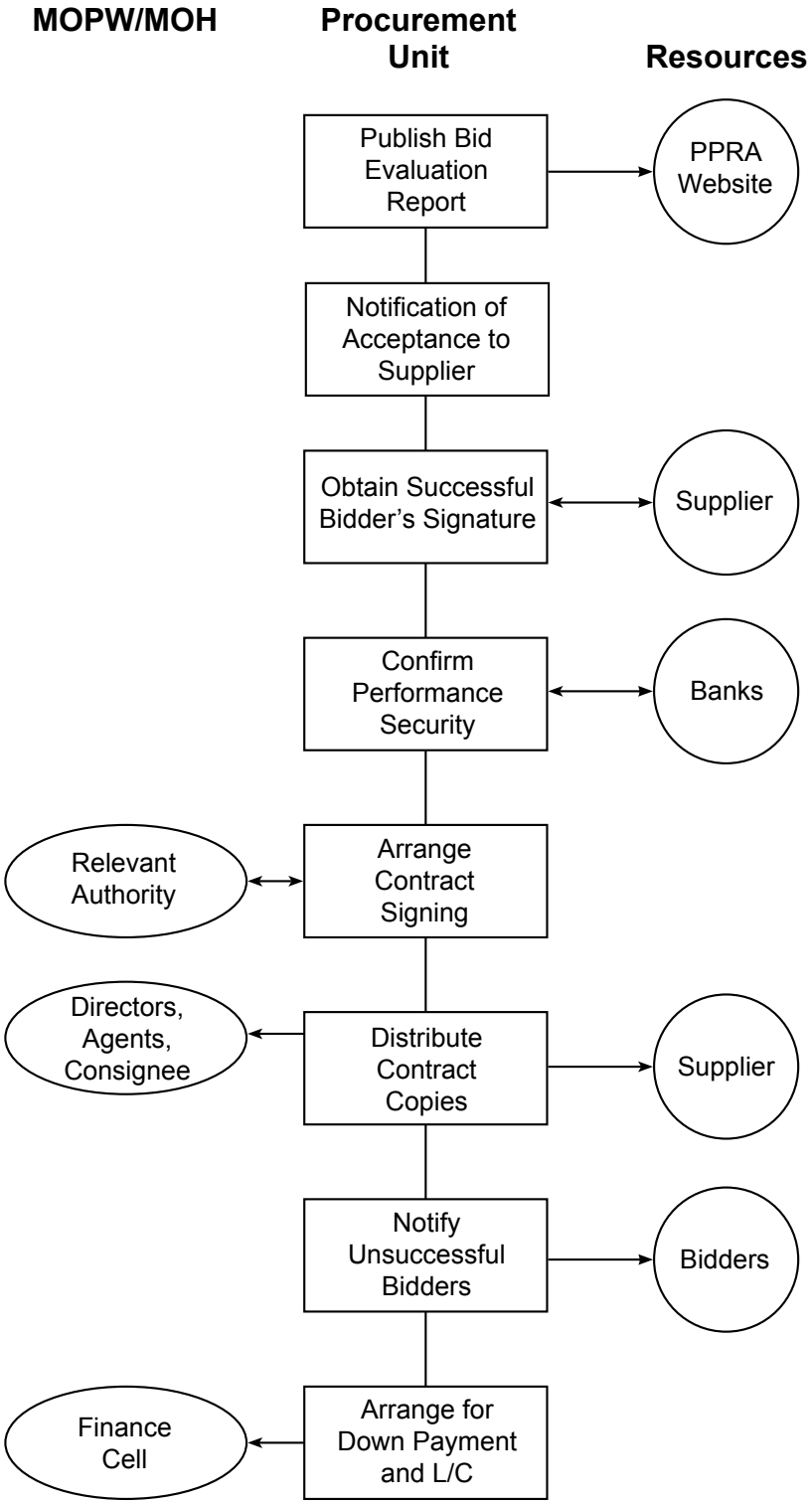
M. Redressal of Grievances

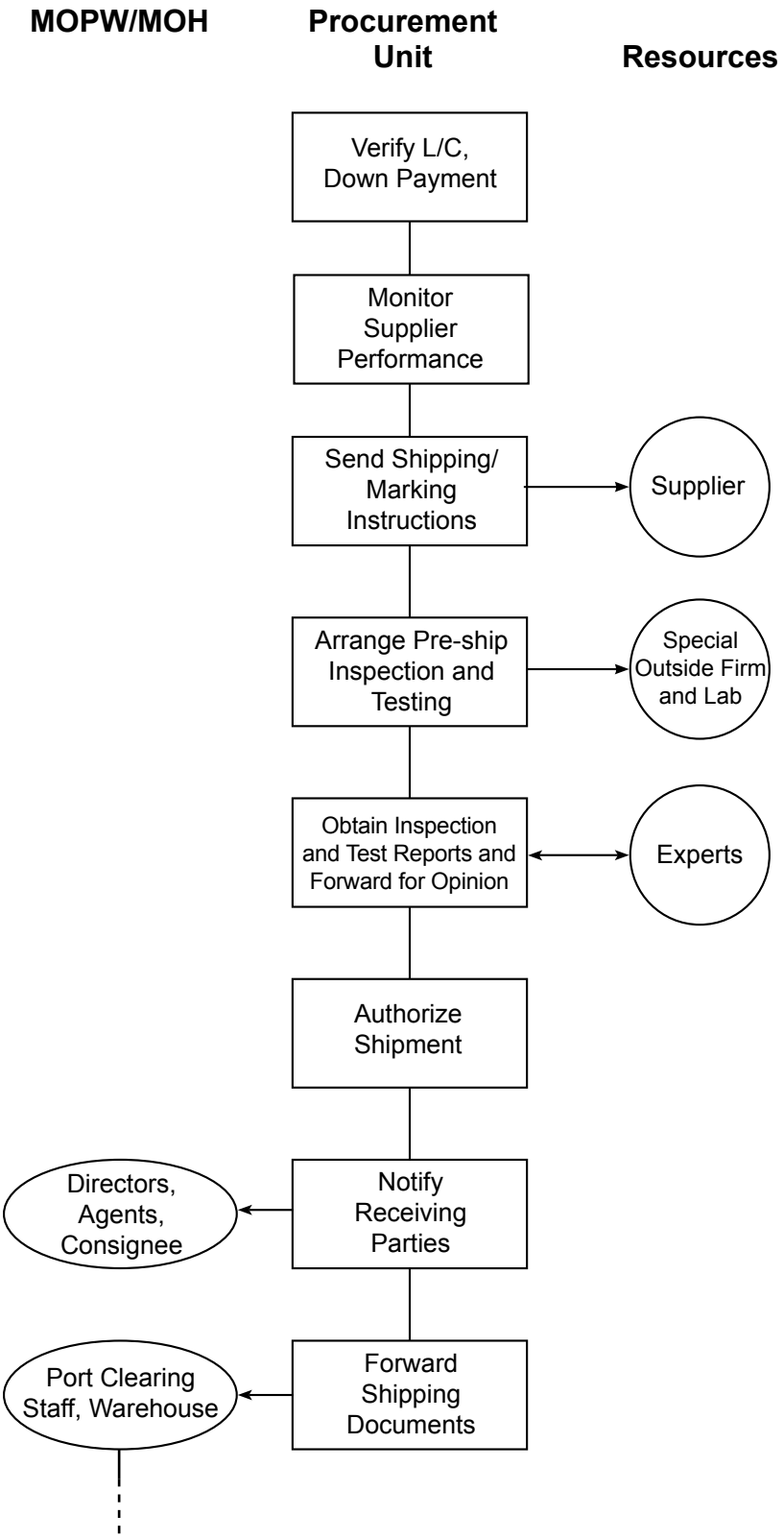
If any bidder should feel that they have not received fair and impartial treatment after submitting their bid, in accordance with PPR 2004 Rule 48, they may file a written complaint no later than 15 days after the announcement of the bid evaluation report.

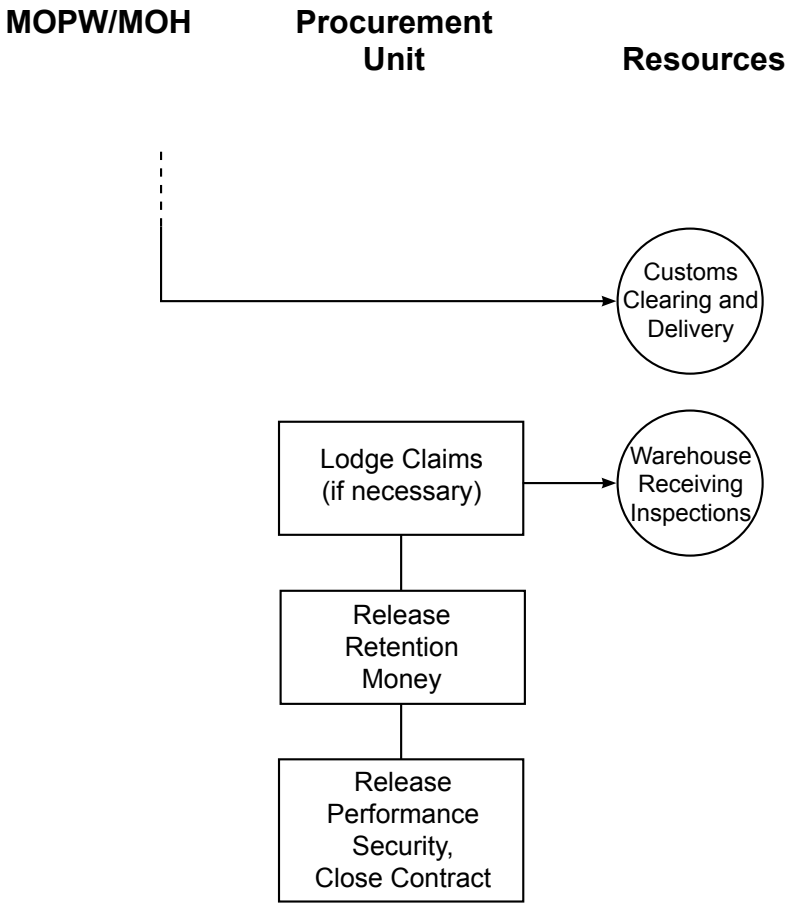
The Grievance Committee, comprising of odd number of person, shall review the grievance and make a decision within 15 days of receipt of the complaint. Lodging a complaint by a bidder does not automatically warrant suspension of the bidding process.

If the bidder is not satisfied with the decision of the Grievance Committee, they have the right to file an appeal in the relevant court of jurisdiction. Grievances so filed shall be settled in line with the requirements of the 1997 Contract Act.

Module V: Award, Contract & Delivery




MOPW/MOH
Procurement Unit
Resources
Verify L/C, Down Payment
Monitor Supplier Performance
Send Shipping/ Marking Instructions
Supplier
Arrange Pre-ship Inspection and Testing
Special Outside Firm and Lab
Obtain Inspection and Test Reports and Forward for Opinion
Experts
Authorize Shipment
Directors, Agents, Consignee
Notify Receiving Parties
Port Clearing Staff, Warehouse
Forward Shipping Documents


MOPW/MOH
Procurement Unit
Resources
Customs Clearing and Delivery
Lodge Claims (if necessary)
Warehouse Receiving Inspections
Release Retention Money
Release Performance Security, Close Contract

This section includes:

A. Publication of Award
B. Notification of Acceptance
C. Performance Security and Contract
D. Payment Arrangements
E. Contract Performance Monitoring
F. Pre-Shipment Inspection and Testing
G. Shipping Clearance and Notifications
H. Shipping Documents
I. Customs Clearance and Delivery
J. Receipt of Consignment
K. Claims and Damages
L. Closing the Contract

A. Publication of Award

The GOP requires the procuring entity to publish award information on their public websites for contracts over Rs 50 million.

1. Submit Award Information to PPRA for Publication

For contracts above Rs 50 million, complete PPRA Contract Award Proforma I (see Annexure 51) and Contract Award Proforma II (see Annexure 52) and submit completed Proformas and any other required information to PPRA for posting on their website at www.ppra.org.pk.

B. Notification of Acceptance

Prior to the expiry of the bid validity period and 10 days after publishing the Contract Award Proformas on the PPRA website, the procuring entity should issue a Notification of Acceptance (NOA) to the successful bidder. The NOA establishes a contract between the procuring entity and the successful bidder, which is confirmed later by signature of the contract document.

1. Prepare Notification Documents

The Notification of Acceptance must state:

a. The acceptance of the bid by the Procuring Agency.

b. The price at which the contract is awarded.

c. The amount of the performance security and its format.

d. The date and time within which the performance security must be submitted.

e. The date and time within which the contract will be signed.

A sample Notification of Acceptance for is provided as Annexure 54.

2. Resolve Minor Deviations

If the recommended bid contains minor[1] deviations that need to be resolved:

2.1 Draft a letter:

- **a.** Stating that the offer is being conditionally accepted pending resolution of outstanding issues.
- **b.** Listing outstanding issues and indicating the next step.
- **c.** Requesting a response/acknowledgement .

2.2 Get concurrence as necessary before sending the letter.

2.3 If deviations are resolved, proceed to award; otherwise select the next lowest evaluated bid approved by the relevant approving authority[2].

3. Send the Notification of Acceptance

The notification of acceptance cannot be sent until ten days after the Contract Award Proformas have been published and the award decision has been approved by the relevant authority.

3.1 Transmit the NOA to the successful bidder by registered post or courier, or by hand delivery. An additional advance notice may be transmitted through e-mail or fax.

3.2 Send copies of the NOA to the local agent of the bidder, if one is stipulated in the bid or advised to the purchasing office at a later time.

C. Performance Security, Contract Signing and Distribution

1. Winning Bidder Submission of Performance Security and Contract Form

1.1 The successful bidder must submit performance security (which should not exceed 10% of contract value) and the signed contract form to the procuring entity within the deadline mentioned in the original bidding documents. The contract form binds him to the general and special conditions of the contract and the specifications contained in the original bidding documents.

- **a.** Normally, the successful bidder goes to the procurement office, hands over the performance security and signs the contract form as first party together with his agent. Alternately, the successful bidder may send the required performance security and signatures via courier.

[1] For example: number of intermediate boxes in a shipping carton, equivalent documentation, differences in shipping schedules, etc.

[2] The 2nd lowest evaluated bid is usually approved by relevant authorities at the same time the winning bid is approved in order to save time if the winning bidder fails to sign a contract or provide performance security.

b. The person who signs the contract for the successful bidder should be the one who signed the bid, or someone who has been authorized in writing for this purpose by the person who signed the bid.

1.2 If the successful bidder fails to meet the deadline mentioned above, his bid security will be forfeited. In this case, the procuring agency should award the contract to the second lowest evaluated bidder.

2. Confirm Performance Security

As soon as the Performance Security is submitted, the procuring agency must get it confirmed by the issuing institution (which is usually a commercial bank).

2.1 Confirm performance securities issued by banks within Pakistan (local issuing banks) by going to the bank and actually speaking with a bank officer.

2.2 Confirm performance securities issued by banks or other institutions outside of Pakistan by e-mail, fax, telegram, telex, letter, etc. The same form and procedure that was used for obtaining confirmation of Bid Securities can be used for Performance Security.

2.3 Confirm performance securities issued by banks outside of Pakistan, but having a correspondent bank within Pakistan, by visiting the correspondent and speaking with a bank officer.

3. Sign the Contract on Behalf of MOPW/MOH

3.1 After the successful bidder signs the contract form and provides performance security, make arrangements for the relevant authority to sign on behalf of MOPW/MOH.

Note

The procuring agency cannot sign the contract until any registration for contraceptives required under the Drug Act of 1976 has been completed. It is critically important for the procurement unit to be aware of registration status and to monitor progress, because Drugs Regulatory procedures can delay contract signing and thus, the delivery date.

4. Distribute and Preserve Contract Originals

4.1 Provide one of the two originals of the signed contract form to the supplier.

4.2 Keep the other original signed contract form, the Performance Security and the bank confirmation letter in a file under proper security and maintenance.

5. Distribute Contract Copies

5.1 Send a copy of the entire signed contact (form plus conditions and specifications, etc.) to the relevant authority for record keeping.

5.2 For international procurement, distribute additional copies of the entire contract as required to the following:

- **a.** Finance Officer
- **b.** Consignee
- **c.** Central Warehouse
- **d.** Port Clearance
- **e.** Clearing and Forwarding Agent
- **f.** Collector of Customs Duties and Collector of Sales Tax at the port of entry
- **g.** Supplier's local agent
- **h.** Project Finance Cell

6. Notify Successful Bidder and Unsuccessful Bidders

Notify the successful bidder and the unsuccessful bidders under PPRA rule 35 and return bid securities to the unsuccessful bidders. Do not take this step until the successful bidder has signed the contract and provided performance security.

See Annexure 4 for detailed information about payment options.

D. Payment Arrangements

Immediately after receiving the signed copy of the contract and confirming the performance security, the procuring agency must initiate arrangements for paying the supplier. This step should not be delayed because most international firms will not begin producing an order until they have received either a down payment or a letter of credit.

1. Arrange Down Payment

If a down payment is required, an official of the procuring agency must request funds from the appropriate financial unit. Direct bank transfer of funds is the best choice for this transaction. It should include:

- **a.** Seller's name, address, bank, account number, address of bank, etc.
- **b.** Reference to procurement contract number.

See Annexure 3 for detailed information about Letters of Credit.

2. Arrange for Opening a Letter of Credit (L/C)

If an L/C is required by the contract, the procurement unit should:

2.1 Seek permission from Pakistan Bank to apply for a Letter of Credit through a specified commercial bank: Letter of Credit Authorization (LCA).

2.2 Assemble the following information and documents:

- **a.** Programme name
- **b.** Contract number
- **c.** Name and address of the beneficiary (seller)
- **d.** Name and address of the beneficiary's bank, or the L/C advising bank as applicable
- **e.** Contract amount and the currency
- **f.** Short description of the contracted goods
- **g.** Any other information pertinent to the L/C application form
- **h.** One copy of the contract
- **i.** One copy of the schedule of requirements

2.3 Develop an L/C instruction sheet from the relevant sections of the contract, giving *precise instructions about the documents against which payment may be made,* shipping schedules, contract amounts, payment schedules, etc. See an example in Annexure 55. The instruction sheet helps to ensure that the L/C will be issued correctly and without delay and that all intended controls, such as conformed test findings, are in place.

2.4 Obtain L/C application forms from the designated commercial bank and prepare a draft application.

2.5 Request the Programme Finance Officer to undertake opening the L/C based on the contract document, application draft and instruction sheet mentioned above.

2.6 Work closely with the Programme Finance Officer, stay informed and provide all possible assistance.

3. Verify Down Payment and/or Letter of Credit

The procurement office should obtain verification that down payment has been made and/or Letter of Credit has been issued.

3.1 Record dates of down payment and L/C issuance.

Based on these dates, the probable shipping date may need to be adjusted, because international suppliers often do not start production until the L/C (or down payment, or both) has been received. Well-constructed contracts always identify from which date the shipping date is to be calculated.

3.2 Obtain a copy of the issued L/C, and confirm that the terms and conditions match the draft application and information provided in step 2.3 above.

4. Facilitate L/C Amendment If Needed

If there are mistakes in the L/C, an amendment will need to be requested.

- **a.** Mistakes by issuing banks are possible. Usually, only a few days are allowed to make corrections without incurring amendment costs. In this case, the purchaser must notify the issuing (commercial) bank.
- **b.** Changes desired by the supplier (called "Beneficiary" in the L/C document) usually require further negotiations. In this case, the purchaser (applicant) requests an amendment from the issuing (commercial) bank, if he agrees with the supplier's (beneficiary's) request. See Annexure 3 for further discussion about letter of credit amendments.

E. Contract Performance Monitoring

It is important for the procurement unit to stay in contact with the manufacturer (supplier) and/or his local agent during the period of manufacture and shipment.

1. Set up and Maintain a Contract Monitoring System

1.1 List responsibilities of the purchaser and of the supplier for contract performance. (See Annexure 56 for a sample list of supplier performance responsibilities.)

- **a.** Responsibilities tied to normal execution of the contract, such as arrangements for inspection, provision of shipping documents, etc.
- **b.** Responsibilities tied to exceptional conditions, such as notification of *force majeure.*

1.2 Establish a probable shipping date based on date of down payment or issuance of L/C and communication with the supplier.

1.3 Develop an estimated schedule for performance of tasks and responsibilities based on the probable shipping date and completion of the contract date. An example is given in Annexure 57.

1.4 Evaluate the status of unfinished orders at least once every two weeks.

- **a.** Update the schedule with the actual dates that tasks and responsibilities are finished.
- **b.** Remind the supplier of upcoming deadlines. Ask how things are progressing.

2. Send Shipping and Marking Instructions

2.1 Produce a separate set of shipping and marking instructions based on the contract document and send it to the supplier at least 30 days, but not more than 60 days, before shipment. This is intended to prevent mistakes by the supplier's warehouse/shipping personnel who may not have access to the contract documents. Clear instructions help to avoid delays and customs clearance problems.

2.2 See Annexure 58 for an example of shipping and marking instructions.

F. Pre-Shipment Inspection and Testing

1. Compliance Programme for Contraceptives and Pharmaceuticals

Contracts for contraceptives and pharmaceuticals from international sources may require special pre-shipment inspection, sampling and testing to verify quality and compliance with specifications before shipping. This is called a "Pre-shipment Compliance Programme". In order to eliminate charges and countercharges of prejudice if there is any disagreement about the outcome of inspection and/or testing, these services should be contracted with specialized, independent third party organizations rather than local government personnel and laboratories, or the supplier's own personnel and laboratories. The purchaser should not only contract for, but also pay for inspection and testing services so that there is less possibility of a supplier influencing the reports. (See Annexure 59 for a sample inspection order.)

"Pre-shipment Compliance Programme," including information on sample size, is described in Appendix VII.

The procurement unit, assisted by a technical expert should make arrangements for any pre-shipment inspection, sampling and testing well ahead of the expected shipping date.

1.1 Ask the technical expert to prepare a separate document for each product that states all requirements for inspection, sampling and testing mentioned in the contract and technical specification. This written "protocol" will serve as detailed instructions to the inspection agent and testing laboratories.

1.2 Contract with qualified inspection, sampling and testing services that have been short-listed by the procuring entity.

1.3 Transmit the inspection and testing protocol (step 1.1 above) to short-listed firms by way of telex/fax/e-mail, etc., and request their rates. Firms or agents that fail to respond to three (3) consecutive requests for rates (e.g., bids) on pending inspections may be dropped from the short-list (provided this condition has been clearly stated in the Invitation for Expressions of Interest (EOI).

1.4 When a supplier indicates that goods are ready for shipment, notify the chosen firm and schedule the inspection (and sampling if required) at the supplier's premises (factory, warehouse, or yard, etc.).

1.5 Compare inspection and test results to the contract requirements and obtain expert opinion on the results of compliance testing. Technical personnel who assisted in development of original specifications and provided input on bid evaluation should be asked to review test results.

a. If there are no differences between specifications and test reports, this step is a formality.

b. If there are differences, the assigned technical expert must decide what to do. The procurement office communicates these decisions to the supplier.

1.6 Check to see that all corrections are made.

a. Re-inspection and re-testing might be required. The purchaser should control these activities, but costs associated with re-inspection and/or re-testing should be paid by the seller.

G. Shipping Clearance and Notifications

1. Authorize Shipment

When test results, expert opinion and review by assigned expert, or committee, have established confidence in the quality and acceptability of the goods proposed for shipment, it is time to authorize shipment.

1.1 Prepare a formal "Authorization to Ship" and forward it to the supplier if he agreed (previously) to include one in the documents required for presentation at his commercial bank for payment through the Letter of Credit . See Annexure 60 for Sample Authorization for Shipment.

2. Provide Pre-Advice to Port Clearance Staff

When a shipping date has been set, informally advise the port clearance staff, warehouse staff and programme managers.

3. Shipper's Notification to Purchaser

As soon as goods have been shipped, the supplier is required (by the contract) to notify the purchaser and provide information on the Bill of Lading (B/L), including:

a. B/L number, vessel, sailing date, and ETA (estimated time of arrival) and destination port, number of crates, weight, value, etc. (equivalent information for Air Waybills).

b. Copies of quality assurance documents and certifications.

c. Copies of commercial documents, including a pro-forma invoice and packing list.

d. Certifications regarding packing and marking.

4. Notifiy Estimated Time of Arrival (ETA)

4.1 Notify the receiving warehouse of the shipment and its ETA. This notification:

a. Allows time to plan warehouse space and inland transportation.

b. Alerts warehouse and logistics staff to upcoming arrival of documents.

4.2 Notify programme management of the ETA date.

H. Shipping Documents

1. Seller's Distribution of Shipping Documents

1.1 For ocean shipments, the supplier hands the goods over to a freight company or freight forwarder and receives the original on-board Bill of Lading. For air shipments, he receives only a copy of the Air Waybill because the original is sent with the goods.

1.2 The Seller puts the original B/L or copy of the Air Waybill together with other documents that are required by the Letter of Credit (L/C) (such as certified quality assurance documents or an authorization for shipment signed by the purchaser) and presents them for payment at the commercial Bank named in the L/C.

2. Consignee's Receipt and Distribution of Shipping Documents

The procuring agency, as the consignee, receives the original negotiated Bill of Lading (in other words, paid) or the Air Waybill copy and other shipping documents (usually, Commercial Invoice, Packing List, and Insurance papers) from the L/C opening bank.

2.1 On receipt of the shipping documents, make copies and distribute as follows:

- **a.** Customs and Forwarding (C and F) Agent (2 sets, one being the negotiable copy)
- **b.** Insurance surveyor (1 set) for marine insurance survey
- **c.** Stores (1 set) for store receipt and store accounting
- **d.** Procurement file (multiple sets)

3. Documents to Karachi for Customs Clearance – Ocean Shipment

For ocean shipments, the procurement office in Islamabad sends a full set of original shipping documents to the Central Warehouse in Karachi for customs clearance as soon as possible. Sending documents late causes delays in port clearance and demurrage charges may need to be paid after delays of as little as four days.

- **a.** Although copies of these documents may have been sent earlier, no goods can be cleared without the signed original Bill of Lading, which is a "negotiable instrument" and must be handled with secure procedures (in other words, protected against theft, loss, forgery, etc.).
- **b.** More than one original plus several copies of the shipping documents are normally required in the terms and conditions of the Letter of Credit. If the purchasing office needs additional certified copies, they should be requested from the L/C opening bank.

4. Documents to Local Customs Broker – Air Shipment

When air-shipments arrive in Karachi, the procurement office should pass the documents on to a local customs broker who should quickly begin clearance procedures.

a. The original Air Waybill accompanies the goods. It does not confer ownership like an ocean Bill of Lading, so only proper identification is required in order to be given possession of the shipment.

b. In some cases, an Exemption Certificate of Customs Duties and VAT (CDVAT) may also be required in order to get a delivery shipment released.

I. Customs Clearance and Delivery

1. Clearance and Delivery Arrangements

As soon as the original shipping documents are received in Karachi, the *port clearing staff* must give the required number of originals and copies to the C and F agent who will arrange for:

a. Payment of port charges

b. Clearance from the port and customs

c. Joint insurance survey, both on board and at the warehouse

d. Insurance claims (if the consignment is insured and found damaged)

e. Loading, offloading and transportation from port to warehouse

2. Pre-Release Inspection

Port clearing staff must work closely with a customs broker and attend any pre- release inspection.

3. Delivery to Receiving Warehouse

Port clearing staff will arrange for delivery to the Central Warehouse, taking all necessary steps to protect the goods.

a. Refrigeration of perishable products (for example, vaccine and insulin)

b. Protection from damage due to bad weather conditions

The customs broker is sometimes able to assist with transportation from the customs area to the receiving warehouse

4. Warehouse Delivery Inspection

Warehouse staff must receive and inspect goods for the following details:

a. Correct commodity

b. Shipping damage

c. Special packing as required by the contract

d. Full quantities delivered

e. Packing slip present and correct

f. Correct markings on packaging, including expiry dates

g. Any further testing required

h. Manufacturer's certifications included with shipment (or documents)

5. Warehouse Reports

Warehouse staff must immediately report any problems found during inspection to appropriate officials.

J. Receipt of Consignment

1. Receiving Consignments of Imports

The *stores department* of the procuring entity will receive the shipment from the C and F agent, along with copies of the following shipping documents:

a. Commercial invoice

b. Packing list

c. Bill of lading or airway bill

d. Certificate of Origin

e. Certificate of Analysis

f. On board insurance survey report (in case the consignment is CIF)

2. Receiving Consignments of Domestic Goods

In case of domestic delivery on Carriage Paid To (CPT) basis, the documents will be copies of:

a. Commercial invoice

b. Packing list

c. Truck receipt

d. Certificate of Analysis

K. Claims and Damages

1. Insurance Claims

If the consignment is received with "qualified remarks," the C and F agent will prepare necessary papers to lodge a marine insurance claim. The papers include:

a. Copy of boat-note

b. Copy of B/L

c. Copy of commercial invoice

d. Copy of packing list

e. Copy of survey report

f. Copy of insurance policy (to be received from the supplier in CIF contracts; to be received from the purchaser in CFR contracts)

g. Claim bill

2. Liquidated Damages

Liquidated damages are usually monetary fines imposed against the supplier for late delivery. When all shipments against the contract are complete:

2.1 Determine if the supplier has accrued any liquidated damages (L/D). This determination process requires a review of:

- **a.** Contract terms and conditions with regard to liquidated damages
- **b.** B/L showing the shipment date (in other words, the date the goods were placed on-board)
- **c.** L/C advice from commercial bank showing the date it was issued
- **d.** Percentage of consignment shipped within the deadlines required by the contract

2.2 If the review reveals late shipment(s) subject to liquidated damages, figure the amount.

3. Adjustment and Release of Retention Money

3.1 Subtract the amount of liquidated damages figured in 2.2 above from the money that has not yet been paid to the supplier (in other words, subtracted from the "retention money"). Retention money does not exceed 10% of the total contracted amount.

3.2 If the amount of the liquidated damages (L/D) is less than the amount of the retention money, the amount remaining after deduction of the L/D amount must be released to the supplier. In this case, the procurement office must:

- **a.** State in writing how exactly L/D applies
- **b.** Figure the amount of L/D, if applicable
- **c.** Advise the supplier of the applicability and amount of L/D
- **d.** Mark invoices for amount to be paid after deduction of the L/D amount, if applicable
- **e.** Send invoice(s) and supporting statements and calculations to the appropriate Finance Office for action

4. Warranty Claims

Check out any complaints or objections that are received from users, and file warranty claims with the supplier, as needed.

L. Closing the Contract

1. Contract Records

At the end of the warranty period, record whether:

- **a.** Any warranty claim(s) have been made, and if they have been settled
- **b.** Any insurance claim was applicable, lodged and realized
- **c.** Any liquidated damages were applicable and, if so, the amount of L/D deducted

2. **Release of Performance Security**
   If there are no outstanding amounts due, claims or other valid reservations, mark the Performance Security "released", issue a letter to the supplier stipulating "no claim" on the Performance Security and send a copy to the bank that issued the Performance Security.

3. **Contract Files**
   Mark the file of the contract "closed" and retain it in the closed file records for a minimum of five years.

Annexures for Procurement Manual

Annexure 1. Government of Pakistan Procurement Policy Guidelines

The following policy guidelines are to be followed for procurement of goods and services.

1. Pakistani suppliers are to be preferred.
2. A domestic price preference may be allowed in line with the Government of Pakistan policy.
3. Goods shall be sourced direct from manufacturers whenever possible.
4. Bids should be evaluated on the basis of best value for money rather than the lowest price.
5. When purchasing drugs and medical supplies, procuring agencies should pre-qualify bidders.
6. When purchasing drugs and medical supplies, procuring agencies should evaluate bids on the basis of appropriate quality rather than lowest price.
7. When the same kind of goods are required on a regular basis, procuring agencies should negotiate framework contracts allowing regular call-off of fresh stock.
8. Where the procurement of goods and services is already pre-approved by the Planning Commission and listed in a programme procuring agency's PC-1, there is no further need to obtain conceptual approval to procure. The PA concerned may proceed to initiate the procurement.
9. Products purchased by programmes should have been available in the market for a minimum period of two years.
10. Response times allowed to bidders should be as stated in the PPR 2004.
11. The amount of security required for bids should be standardised at 3.5% of the bidder's offer in single stage bids.
12. When two-envelope bidding is employed, the bid security shall be submitted with the first (technical proposal) envelope to be opened so that non-responsive bids may be immediately rejected before technical evaluation.
13. When two-envelope bidding is employed, the amount of bid security required shall be a fixed amount common to all bidders. This fixed amount shall be 3.5% of the PA's budget for the procurement concerned.
14. The amount of security required for performance guarantees shall be standardised at 8% of contract value.

Annexure 2. INCOTERMS 2000

Note

Carrier means any person who, in a contract of carriage, undertakes to perform or to procure the performance of carriage by rail, road, sea, air, inland waterway or by a combination of such modes. If the Buyer instructs the Seller to deliver the cargo to a person, e.g., a freight forwarder who is not a "carrier", the Seller is deemed to have fulfilled his obligation to deliver the goods when they are in the custody of that person.

Transport terminal means a railway terminal, a freight station, a container terminal or yard, a multi-purpose cargo terminal or any similar receiving point.

Container includes any equipment used to unitize cargo, e.g., all types of containers and/or flats, whether ISO accepted or not, trailers, swap bodies, RoRo-equipment or igloos, and applies to all modes of transport.

Group E: Departure Term

1. **EXW …named place**
   EXW ("EX Works…") means that the Seller fulfills his obligation to deliver when he has made the goods available at his premises (i.e., works, factory, warehouse, etc.) to the Buyer. In particular, he is not responsible for loading the goods on the vehicle provided by the Buyer or for clearing the goods for export, unless otherwise agreed in the purchase contract. The Buyer bears all costs and risks involved in taking the goods from the Seller's premises to the desired destination. This term thus represents the minimum obligation for the Seller.

   EXW should not be used when the Buyer cannot carry out export formalities directly or indirectly. In such circumstances, the FCA term should be used.

Group F: Shipment Terms – Main Carriage Paid By Buyer

2. **FCA …named place**
   FCA ("Free Carrier…") means that the Seller fulfills his obligation to deliver when he has handed over the goods, cleared for export, into the charge of the carrier named by the Buyer at a named place or point of departure. If delivery occurs at the Seller's premises, the Seller is responsible for loading. If delivery occurs at any other place, the Seller is not responsible for unloading. If no precise point is indicated by the Buyer, the Seller may choose within the place or range stipulated where the carrier shall take the

goods into his charge. When, according to commercial practice, the Seller's assistance is required in making the contract with the carrier (such as in rail or air transport), the Seller may act at the Buyer's risk and expense.

FCA may be used for any mode of transport, including multi-modal transport.

3. **FAS …named port of shipment**
   FAS ("Free Alongside Ship…") means the Seller fulfills his obligation to deliver when the goods have been placed alongside the vessel on the quay or in lighters at the named port of shipment. From that moment, the Buyer has to bear all costs and risks of loss of or damage to the goods. The FAS term requires the Seller to clear the goods for export and the Buyer to carry out customs formalities for import.

   FAS can only be used for sea or inland waterway transport.

4. **FOB …named port of shipment**
   FOB ("Free on Board…") means the Seller fulfills his obligation to deliver when the goods have passed over the ship's rail at the named port of shipment. From that moment on, the Buyer has to bear all costs and risks of loss of or damage to the goods. The FOB term requires the Seller to clear the goods for export.

   FOB can only be used for sea or inland waterway transport. When the ship's rail serves no practical purpose, such as in the case of roll-on/roll-off or container traffic, the FCA term should be used.

Group C: Shipment Terms – Main Carriage Paid By Seller

Under Group C terms, there are two critical division points, one for the division of *costs,* the other for the division of *risk*. Costs are assumed by the Seller, until the destination point; risks are transferred to the Buyer at the point of shipment.

5. **CFR…named port of destination**
   CFR ("Cost and Freight…") means the Seller must pay the costs and freight necessary to bring the goods to the named port of destination but the risk of loss or damage to the goods, as well as any additional costs due to events occurring after the time the goods have been delivered on board the vessel, is transferred from the Seller to the Buyer when the goods pass the ship's rail in the port of shipment. The CFR term requires the Seller to clear the goods for export.

   CFR can only be used for sea and inland waterway transport. When the ship's rail serves no practical purpose, such as in the case of roll-on/roll-off or container traffic, the CPT term is more appropriate.

6. **CIF …named port of destination**
   CIF ("Cost, Insurance and Freight…") means the Seller has the same obligations as under CFR but with the addition that he has to procure marine insurance against the

Buyer's risk of loss of or damage to the goods during the carriage. The Seller contracts for insurance and pays the insurance premium, but the Seller is only required to obtain insurance on minimum coverage. The CIF term requires the Seller to clear the goods for export.

CFR can only be used for sea and inland waterway transport. When the ship's rail serves no practical purposes, such as in the case of roll-on/roll off or container traffic, the CIP term should be used.

7. **CPT …named place of destination**
CPT ("Carriage Paid To…") means the Seller pays the freight for the carriage of the goods to the named destination. The risk of loss or damage to the goods, as well as additional costs due to events occurring after the time the goods have been delivered to the carrier, is transferred from the Seller to the Buyer when the goods have been delivered into the custody of the carrier. If subsequent carriers are used for the carriage to the agreed destination, the risk passes when the goods have been delivered to the first carrier. The CPT term requires the Seller to clear the goods for export.

CPT may be used for any mode of transport, including multi-modal transport.

8. **CIP …named place of destination**
CPT ("Carriage and Insurance Paid to…") means the Seller has the same obligations as under CPT but with the addition that the Seller has to procure cargo insurance against the Buyer's risk of loss of, or damage, to the goods during the carriage. The Seller contracts for insurance and pays the insurance premium. The Buyer should note that under the CIP term the Seller is only required to obtain insurance on minimum coverage. The CIP term requires the Seller to clear the goods for export.

This term may be used for any mode of transport, including multi-modal transport.

Group D: Arrival Terms

9. **DAF …named place**
DAF ("Delivered at Frontier…") means the Seller fulfills his obligation to deliver when the goods have been made available, cleared for export at the named point and place at the frontier, but before the customs border of the adjoining country. The term "frontier" may be used for any frontier, including that of the country of export. Therefore, it is of vital importance that the frontier in question be defined precisely by naming the point and place in the term.

This term is primarily used when goods are to be carried by rail or road, but it may be used for any mode of transport.

10. DES …named port of destination

DES ("Delivered Ex Ship…") means the Seller fulfills his obligation to deliver when the goods have been made available to the Buyer on board the ship, but *not* cleared for import at the named port of destination. The Seller has to bear all the costs and risks involved in bringing the goods to the named port of destination.

This term can only be used for sea or inland waterway transport.

11. DEQ …named port of destination

DEQ ("Delivered Ex Quay…") means the Seller fulfills his obligation to deliver when he has made the goods available to the Buyer on the quay (wharf) at the named port of destination, but not cleared for importation. The Seller has to bear all risks and costs involved in bringing the goods to the named port of destination and discharging the goods on the quay (wharf), including duties, taxes and other charges of delivering the goods thereto.

If the parties wish to exclude from the Seller's obligations some of the costs payable upon importation of the goods (such as value added tax – VAT), this should be made clear by adding the words to this effect: "Delivered ex quay, VAT unpaid (named port of destination)".

This term can only be used for sea or inland waterway transport. It should not be used if the Seller is unable, directly or indirectly, to obtain the import license.

12. DDU …named place of destination

DDU ("Delivered Duty Unpaid…") means the Seller fulfills his obligation to deliver when the goods have been made available at the named place in the country of importation. The Seller has to bear the costs and risks involved in bringing the goods thereto (excluding duties, taxes and other official charges payable upon importation) as well as the costs and risks of carrying out customs formalities. The Buyer has to pay any additional costs and to bear any risks caused by his failure to clear the goods for import in time.

If the parties wish the Seller to carry out customs formalities and bear the resulting costs and risks, this has to be made clear by adding words to this effect.

If the parties wish to include in the Seller's obligations some of the costs payable upon importation of the goods (such as VAT), this should be made clear by adding words to this effect: "Delivered duty unpaid, VAT paid (…named place of destination)".

This term may be used irrespective of the mode of transport.

13. DDP …named place of destination

DDP ("Delivered Duty Paid…") means the Seller fulfills his obligation to deliver when the goods have been made available at the named place in the country of importation, but not unloaded. The Seller has to bear the risks and costs, including duties, taxes and other charges of delivering the goods thereto, cleared for importation. If the parties wish to exclude from the Seller's obligations some of the costs payable upon importation of the goods (such as VAT), this should be made clear by adding words to this effect: "Delivered duty paid, VAT unpaid (…named place of destination)".

This term may be used irrespective of the mode of transport.

INCOTERMS: Responsibilities of Buyers and Sellers

The following table explains the responsibilities of Buyers and Sellers for each of the INCOTERMS. For a given term, "Yes" indicates that the seller has the responsibility to provide the service included in the price. "No" indicates it is the buyer's responsibility. If insurance is not included in the term (for example, CFR), then insurance for transport is the responsibility of the buyer or the seller depending on who owns the cargo at time of transport. In the case of CFR terms, it would be the buyer while in the case of DDU or DDP terms, it would be the seller.

	Load to truck	Export-duty payment	Transport to exporter's port	Unload from truck at the origin's port	Landing charges at origin's port	Transport to import's port	Landing charges at importer's port	Unload onto trucks from the importers' port	Transport to destination	Insurance	Entry - Customs clearance	Entry - Duties and Taxes
EXW	No	No	No	No	No	No	No	No	No	No	No	No
FCA	Yes	Yes	Yes	No	No	No	No	No	No	No	No	No
FAS	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No
FOB	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No
CFR	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No
CIF	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	No	No
CPT	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No
CIP	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	No	No
DAF	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No	No
DES	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	No	No
DEQ	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	No	No
DDU	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No
DDP	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Annexure 3. Letters of Credit

This four-page Annexure presents the very basic elements of Letters of Credit – shown in both written and graphic form.

Opening a Letter of Credit

The Buyer applies to his commercial bank to issue a Letter of Credit in favour of the Seller. Exact terms are spelled out, such as:

- How much is to be paid
- In what currency
- Time limits for shipment, presentation of documents for payment
- What documents must be presented in order to allow the bank to pay

In most cases, the Buyer (who is now the "Applicant") will be required to deposit funds or assign already deposited funds equal to the expected payment. This is called "collateralizing" the Letter of Credit. During the period between deposit and payment, the bank may pay the Buyer (Applicant) interest, or other benefit, for the use of the funds deposited with the bank.

In the case of GoB and the HNPSP credit, there are two options for collateralizing the Letter of Credit. One uses funds already residing in GoB's bank accounts. The other uses a World Bank guarantee, mainly for very high value contracts.

The commercial bank issues its document to the Seller (Beneficiary) with a copy to the Buyer (Applicant). If there are errors in the document prepared by the bank, a no-cost amendment can be requested. Amendments can also be requested either by the Buyer or the Seller to accommodate changing conditions, provided the changes are acceptable to both parties. For instance, a delivery date may need to be amended based on an agreement between Seller and the Buyer.

Cost of Opening a Letter of Credit

Banks charge a percentage of the value of the goods for opening the Letter of Credit. This charge is normally paid by the Applicant (Buyer). Banks levy additional fees for amendments, payments and draw-downs. The Letter of Credit should stipulate who is responsible for paying these additional fees, the Beneficiary or the Applicant. Fees for opening a Letter of Credit will amount to at least several hundred dollars. Since every bank is different, the Applicant should get this information at the initial contact. A typical fee ranges from 0.5 percent to 1.0 percent of the face value of the Letter of Credit.

Settling a Letter of Credit

In order to receive payment, the Beneficiary (Seller) must submit specified documents to the paying bank as proof of his performance. These documents are:

- Commercial Invoice
- Insurance Certificate
- Transport Documents (for example, the Bill of Lading or Air Waybill)
- Certificate of Origin
- Inspection Certificate
- Other Certificates and Certifications (for example, Certificate of Analysis)

The first three items are required. The last three items are optional and are often used by the purchaser as tools to enforce contract provisions.

Additional information on Letters of Credit is located in Annexure 3 Payment Options.

Figure 1

Opening a Letter of Credit

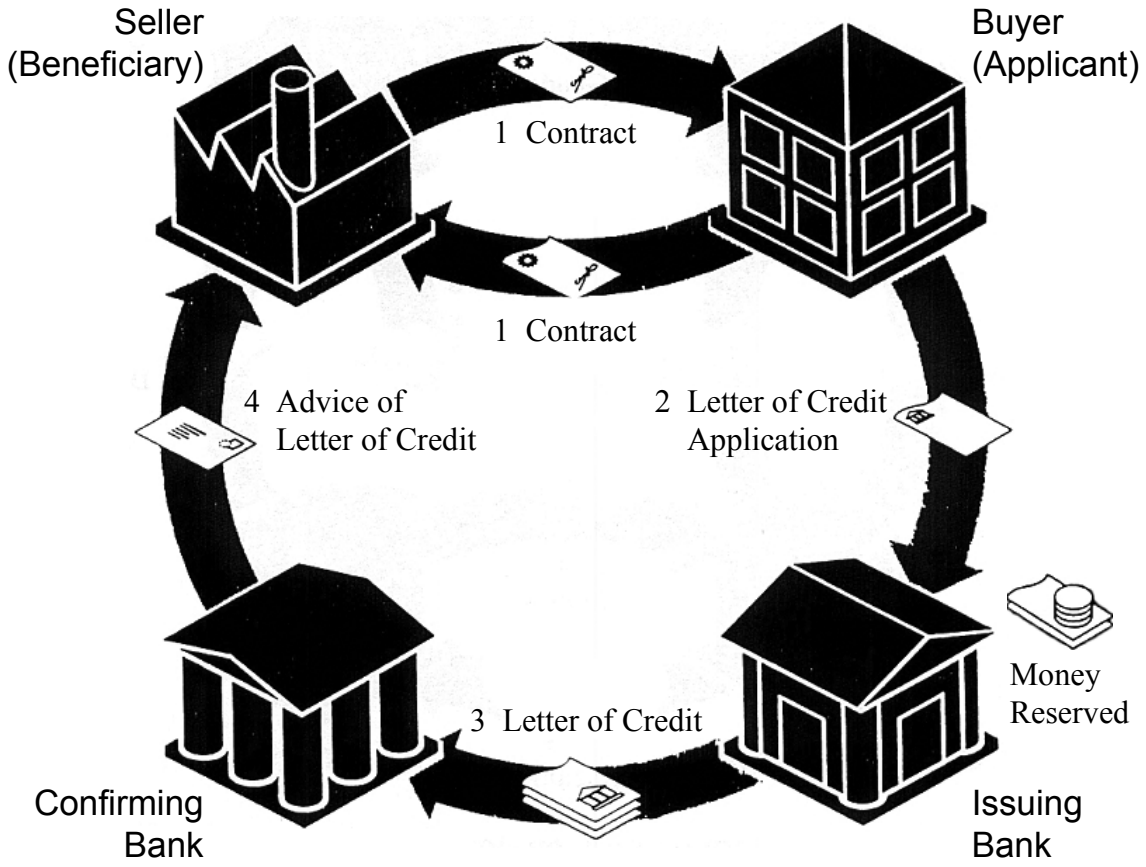
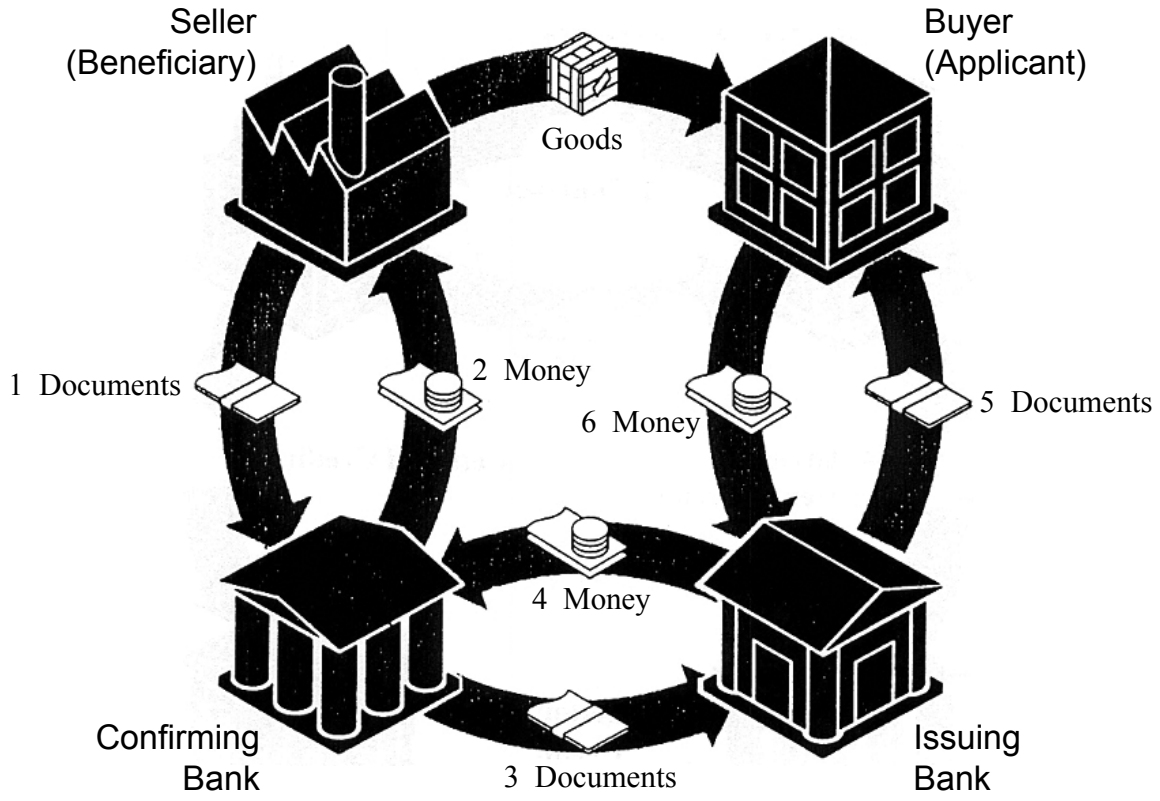


Figure 2

Paying (Settling) a Letter of Credit



Annexure 4. Payment Options

Payment Options

The Seller generally dictates payment terms, but the Buyer is free to negotiate. The most common payment terms are:

- Cash in advance
- Down payment
- On account
- Payment against documents
- Letter of Credit

1. **Cash in Advance**
   The Buyer, after purchasing the commodity under the original contract, sends the Seller cash pre-payment for the entire shipment. The Seller, upon receipt of the cash advance, makes shipment to the Buyer and provides all the necessary shipping documents. This is the simplest payment option.

   What are the advantages and disadvantages of cash in advance?
   This method of payment involves direct Buyer/Seller contact without commercial bank involvement and is, therefore, inexpensive. However, the Buyer faces a very high degree of payment risk while retaining little recourse against the Seller for poor quality goods or incorrect or incomplete documentation, and there is a possibility that an unscrupulous Seller may never deliver the goods even though the Buyer has made full prepayment.

2. **Down payment**
   The Buyer pays the Seller a portion of the cost of the goods "in advance", when the contract is signed or shortly thereafter.

   What are the advantages and disadvantages of down payment?
   The down payment method induces the Seller to begin performance without the Buyer paying all agreed price in advance. The disadvantage is that there is a possibility the Seller may never deliver the goods even though it has the Buyer's down payment. This option must be combined with one of the other options to cover the full cost of goods.

3. **Open account or "on account"**
   This payment method is virtually the opposite of "cash in advance". In this option, the Seller essentially extends credit to the Buyer. Upon shipment, the Seller prepares the normal documents (such as bills of lading and original invoices) and presents these to the Buyer directly, thus avoiding the involvement of a commercial bank. The Buyer then pays the Seller directly, usually via wire transfer, upon receipt of the documents.

What are the advantages and disadvantages of open account?
Under an open account payment method, title to the goods usually passes from the Seller to the Buyer prior to payment and subjects the Seller to risk of default by the Buyer. Furthermore, there may be a time delay in payment, depending on how quickly documents are exchanged between Seller and Buyer. While this payment term involves the fewest restrictions and the lowest cost for the Buyer, it also presents the Seller with the highest degree of payment risk and is employed only between a Buyer and a Seller who have a long-term relationship involving a great level of mutual trust.

4. Payment against documents

This method of payment is primarily used for ocean shipment. It is generally inapplicable for goods shipped by air since they would arrive well before the documents.

How does payment against documents work?

Under the original contract, the Seller makes shipment and then sends the shipping documents to his bank for collection. The Seller's bank sends the shipping documents along with a collection letter to the Buyer's bank which, in turn, sends a collection notice to the Buyer. The Buyer either makes payment upon receiving the notice and prior to possessing the shipping documents (a cash against documents arrangement), or the Seller accepts a time draft obligating the Buyer to pay at a future date (a documents against acceptance arrangement). Only after payment or acceptance does the Buyer receive the original shipping documents, which confer title to the goods.

What are the advantages and disadvantages of payment against documents?
The major advantage of a "cash against documents" payment method for the Buyer is the low cost, versus opening a Letter of Credit. The advantage for the Seller is that he can receive full payment prior to releasing control of the documents, although this is offset by the risk that the Buyer will, for some reason, reject the documents (or they will not be in order). Since the cargo would already be loaded (to generate the documents), the Seller has little recourse against the Buyer in cases of non-payment. A payment against documents arrangement involves a high level of trust between the Seller and the Buyer and should be adopted only by parties well known to each other.

5. Letter of Credit

There are three major types of Letter of Credit: revocable Letter of Credit, irrevocable Letter of Credit and confirmed irrevocable Letter of Credit. This manual discusses only the latter two because revocable is rarely used.

a. Irrevocable Letter of Credit

The irrevocable commercial Letter of Credit is a banking instrument that guarantees payment to the Seller (Beneficiary) when he has complied with its terms. Usually, these terms will include shipment of the contracted goods, compliance with specific

contract requirements and presentation of specified documentary evidence to the bank proving compliance. The bank deals in documents only, not intentions, and, therefore, allows no discrepancies without the expressed approval of the Buyer (Applicant).

b. Confirmed Irrevocable Letter of Credit

The Seller relies on the bank's guarantee and, therefore, wants to be completely assured of its reliability. When Letters of Credit are issued through small local banks, the confirmation of a major international bank is often required. In other cases, the Seller simply wants payment to be guaranteed by a bank located in his own country. Thus, a "Confirmed" Letter of Credit is a double assurance of payment: the Issuing Bank makes a legally binding promise to pay a Beneficiary and a second bank (the Confirming Bank) adds its own legally binding guarantee to pay if the Issuing Bank defaults.

In selecting a bank to issue a Letter of Credit, it is important to choose one with an official correspondent relationship with a major international bank so that appropriate confirmations are possible.

Separate Contracts Relating to Letters of Credit

There are three separate contracts in operation under a Letter of Credit arrangement and sometimes four. Each contract is independent and controls its relationship with the other parties:

- The sales contract between the Buyer and the Seller.
- The reimbursing agreement between the Buyer (Applicant) and the Issuing Bank (the Bank that issues the Letter of Credit) normally a deposit or set-aside of the Buyer's (Applicant's) funds in his own bank against the time the Seller (Beneficiary) fully complies with the requirements of the Letter of Credit and thus gains access to the payment. The Buyer (Applicant) is said to have "collateralized" the Letter of Credit when he deposits or sets aside funds in the Issuing Bank. These funds may not be used for other purposes, but the Buyer (Applicant) earns interest, or other benefit, on the deposit until the Letter of Credit is paid.
- The Letter of Credit between the Issuing Bank and the Beneficiary (Seller).
- If the Letter of Credit is "confirmed" by another bank, then such bank (the Confirming Bank) undertakes its own contractual arrangement with the Beneficiary (Seller), in addition to that of the Issuing Bank.

Role of Advising Bank

An Advising Bank simply provides information and there is no contractual undertaking. In practice, however, the Advising Bank may also be the Confirming Bank.

Advantages and Disadvantages of Letters of Credit

The Letter of Credit allows the Buyer to avoid payment in advance, accrue interest (or other consideration) on deposited funds until the goods are shipped and enforce quality assurance provisions in the contract by linking proof of compliance to payment. This proof may take the form of Quality Assurance Documents, Inspection or Testing Certificates or an Authorization for Shipment signed by the Buyer's representative, based on acceptable inspection or testing results.

The confirmed, irrevocable Letter of Credit presents the Seller with the least risk. Since the Buyer generally bears the cost of opening the Letter of Credit, it is the highest cost option for the Buyer. In addition, the existence of a Letter of Credit does not obligate the Seller to ship the goods purchased by the Buyer.

Annexure 5. Code of Business Ethics

Legal Reference: Procurement Rules 2004: Rule 2 Definition Sub-Rule (1)(f) Corrupt and Fraudulent Practices. The Code of Business Ethics is applicable to public sector procurement for Reproductive Health Family Planning programmes.

"An employee shall not use his authority or office for personal gain. Personal gain includes accepting or requesting anything of material value from bidders, prospective bidders or suppliers for the employee, his spouse, parents, children or other close relatives, or for other persons from whom the employee might gain direct or indirect benefit from the gift."

1. **Ethical Principles**
   Based on the above legal requirement for GOP employee behaviour, all employees shall seek to maintain and enhance the reputation of the Government of Pakistan by:
   - Maintaining the highest standards of honesty and integrity in all relationships both inside and outside the programme in which he works;
   - Developing the highest possible standards of professional competence;
   - Using funds and other resources for which he is responsible to provide the maximum benefit to the programme and the Government; and
   - Complying with both the letter and the spirit of:

     The laws, rules and regulations of the Islamic Republic of Pakistan

     Accepted professional ethics

     Contractual obligations

2. **Conflict of Interest**
   All employees shall declare any personal interest they may have in any procurement that may affect, or may reasonably be deemed by others to affect, their impartiality in any matter relevant to their duties.

3. **Confidentiality and Accuracy of Information**
   All employees shall respect the confidentiality of information gained in the course of their duties and shall not use such information for personal gain or for the unfair benefit of any bidder or supplier.

   Information given by an employee of a national programme in the course of his duty shall be true, fair and not designed to mislead.

4. **Competition**
   All employees shall treat all bidders and suppliers with fairness and impartiality, and avoid any business arrangement that might prevent the effective operation of fair competition.

5. Business Gifts

No employee shall accept business gifts from current or potential suppliers unless such gifts are of a very small intrinsic value such as a calendar or business diary.

6. Hospitality

All employees shall refrain from accepting any business hospitality that might be viewed by others as having an influence in making a business decision as a result of accepting that hospitality.

7. Reporting

All employees have a duty to report any unethical conduct by a colleague, a bidder or a supplier to their superiors or to the auditors. Examples of unethical conduct include:

- Revealing confidential or "insider information" either directly or indirectly to any bidder or prospective bidder.
- Discussing a procurement with any bidder or prospective bidder outside the official rules and procedures for conducting procurements.
- Favouring or discriminating against any bidder or prospective bidder in the drafting of technical specifications or standards or the evaluation of bids.
- Destroying, damaging, hiding, removing or improperly changing any official procurement document.
- Accepting or requesting any money, travel, meals, entertainment, gifts, favours, discounts or anything of material value from bidders or prospective bidders.
- Discussing or accepting future employment with a bidder or prospective bidder.
- Requesting any other employee or Government official representing the procuring agency in a procurement to violate the public procurement rules or procedures.
- Ignoring evidence that the Code of Ethics has been violated by a member of a Bid Review Committee, a civil servant or any other employee or representative of the procuring agency.
- Ignoring illegal or unethical activity by bidders or prospective bidders, including any offer of personal inducements or rewards.

بسم اللہ الرحمن الرحیم

From : Mr. Sajid Hassan
Addl. Finance Secretary(Exp)/MD
Tele: 9201496

Ministry of Finance
Government of Pakistan

Public Procurement Regulatory Authority

Islamabad the 5-10-2002
P.C. 44000

D.O.No.F.3(7)/2002/PPRA

Subject:- DECLARATION OF FEES, COMMISSIONS AND BROKERAGE ETC., PAYABLE BY THE SUPPLIERS OF GOODS, SERVICES AND WORKS

My dear Secretary

I am directed to say that in a meeting of the Economic Coordination Committee of the Cabinet held on 23rd September, 2002 the question of adoption of good procurement practices by the public sector agencies was discussed. After due discussion, it was decided that all the public sector agencies, whether attached/subordinate or autonomous working under a Ministry will always demand a certificate, as attached herewith, while procuring goods & services worth Rs 10 million or more. This certificate inter alia, will be checked by the Auditors at the time of audit. This requirement is mandatory and may be complied with in all circumstances.

2. You are requested to convey this decision to all attached Departments, Subordinate Offices, Autonomous/Semi Autonomous Bodies and Corporations etc., working under your Ministry for strict compliance.

With regards,

Yours sincerely,

(Sajid Hassan)

All Secretaries to the Ministries/Divisions.

Integrity Pact

DECLARATION OF FEES, COMMISSION AND BROKERAGE ETC. PAYABLE BY THE SUPPLIERS OF GOODS, SERVICES & WORKS IN CONTRACTS WORTH RS.10.00 MILLION OR MORE

Contract Number: _____ Dated:_____

Contract Value: _____

Contract Title: _____

_____ [name of Supplier] hereby declares that it has not obtained or induced the procurement of any contract, right, interest, privilege or other obligation or benefit from Government of Pakistan or any administrative subdivision or agency thereof or any other entity owned or controlled by it (GoP) through any corrupt business practice.

Without limiting the generality of the foregoing, _____ [name of Supplier] represents and warrants that it has fully declared the brokerage, commission, fees etc. paid or payable to anyone and not given or agreed to give and shall not give or agree to give to anyone within or outside Pakistan either directly or indirectly through any natural or juridical person, including its affiliate, agent, associate, broker, consultant, director, promoter, shareholder, sponsor or subsidiary, any commission, gratification, bribe, finder's fee or kickback, whether described as consultation fee or otherwise, with the object of obtaining or inducing the procurement of a contract, right, interest, privilege or other obligation or benefit in whatsoever form from GoP, except that which has been expressly declared pursuant hereto.

_____ [name of Supplier] certifies that it has made and will make full disclosure of all agreements and arrangements with all persons in respect of or related to the transaction with GoP and has not taken any action or will not take any action to circumvent the above declaration, representation or warranty.

_____ [name of Supplier] accepts full responsibility and strict liability for making any false declaration, not making full disclosure, misrepresenting facts or taking any action likely to defeat the purpose of this declaration, representation and warranty. It agrees that any contract, right, interest, privilege or other obligation or benefit obtained or procured as aforesaid shall, without prejudice to any other right and remedies available to GoP under any law, contract or other instrument, be voidable at the option of GoP.

Notwithstanding any rights and remedies exercised by GoP in this regard, _____ [name of Supplier] agrees to indemnify GoP for any loss or damage incurred by it on account of its corrupt business practices and further pay compensation to GoP in an amount equivalent to ten time the sum of any commission, gratification, bribe, finder's fee or kickback given by _____ [name of Supplier] as aforesaid for the purpose of obtaining or inducing the procurement of any contract, right, interest, privilege or other obligation or benefit in whatsoever form from GoP.

_____ [Buyer]

_____ [Seller/Supplier]

Annexure 6. Procurement Plan Format

PROCUREMENT PLAN

Ministry / Division:

Agency:

Procuring Entity Name & Code:

Project/ Programme Name & Code:

BUDGET:

Package No.	Description of Procurement Package	Unit	QTY	Procurement Method and Type	Contract Approving Authority	Source of Funds	Est. Cost in Rupees	Timeline	Advertise Tender	Tender Opening	Tender Evaluation	Approval to Award	Notification of Award	Signing of Contract	Completion of Contract	Total Time (in days)
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Example	Oral contraceptives, combined estrogen and progestin low-dose; Monthly packet shall contain 28 tablets, 7 tablets shall contain ferrous fumarate	packet	14.5 M	ICB	Ministry	GOP	430 M	Planned Dates	24-May-10	5-Jul-10	26-Jul-10	9-Aug-10	16-Aug-10	15-Sep-10	13-Jan-11	
								Planned Days	0	42	21	14	7	30	120	234
								Actual Dates								
								Planned Dates								
								Planned Days								
								Actual Dates								
								Planned Dates								
								Planned Days								
								Actual Dates								
								Planned Dates								
								Planned Days								
								Actual Dates								
Total Value of Goods																

Annexure 7. Financial Thresholds

Procurement Method	Source of invitation for bids	Thresholds* (As per PPR-2004 of GOP) in PKR	Remarks
Petty Purchase	No bid or quotation; only Invoice from single source	1/- to 24,999/-	Should be in accordance with Rule-4 (Principles of Procurement)
Request for Quotation (RFQ)	Minimum three quotations	25,000/- to 99,999/-	The object of procurement should have standard specifications
Direct Contracting			For all direct contracting and single source selection the rules prescribed by PPR 2004 apply
National Competitive Bidding (NCB)	Advertise on PPRA website	100,000/- to 2,000,000/-	It can also be advertised through print media if deemed necessary (most of potential bidders may not have access to the NET)
National Competitive Bidding (NCB)	Print media (newspapers with wide circulation) as well as websites of PPRA and procuring agency	Over 2,000,000/-	At least two national dailies; English and Urdu. PPRA is silent on upper limit for NCB
International Competitive Bidding (ICB)			PPR 2004 does not provide details about financial thresholds for international procurements; however we assume the same for NCB

Annexure 8. Estimated Timeline

Estimated Timeline for High Value Procurement			
4 months or more for budgeting & planning precedes initiation of procurement package			
	In days	**In weeks**	**In months**
Initiate Procurement	30	4	
Set up file	2		
Gather Pertinent Information	25		
Summarize Data	3		
Develop Bid Documents	45	6	
Draft ITB, SC, Specs, Reqmts	45		
Solicit Receive & Open Bids	56	8	
Place Advertisement & Notify	10		
Sell Bidding Docs	45		
Hold Public Bid Opening	1		
Evaluate Bids Obtain Approvals	60	9	
Complete Std Bid Evaluation	60		
Notify Award	7	1	
Receive Performance Security			
Sign Contract	21	3	
Open L/C	14	2	
Manufacturing Lead Time	112	16	
Pre-shipment Quality Check	13	2	
Inspect at Supplier’s Premises	1		
Testing	10		
Authorize Shipment	2		

Estimated Timeline for High Value Procurement			
Shipping	40	6	
Delivery	6	1	
Import Procedures	5		
Receiving Inspection	1		
Acceptance Cert.			
Total	**404**	**58**	**13.5**

Annexure 9. Procurement Requisition Form

Name of Procuring Agency

Form SPF 1
Page __of ___

Procurement Number					
Entity	**Department/Project**	**Financial Year**	**Sequence Number**	**Bid Number**	**Contract Number**
Subject of Procurement:				**Location/Site:**	

Item No.	Description *(A detailed Statement of Requirements or Stock Management Information may be attached)*	Quantity	Unit of Measure	Estimated Unit Cost	Estimated Total Cost

Funds Availability:	Chapter	Section	Item	Type

Estimated Total Cost:	

Signatures required to certify that (1) the works, services or supplies described are required, (2) approval is granted to proceed with the procurement, and that (3) funds are available or budgeted for the requirement.

	1. Originating Officer	2. Head of Department/Unit	3. Finance Section Officer
Signature:			
Name:			
Position:			
Date:			

Annexure 10. Procurement Requisition Form Information

This annexure contains information on preparing a procurement requisition and a sample procurement requisition form. This information has been taken from the document "Manual of Procurement Policies and Standard Operating Procedures for the NHF Programmes of the Ministry of Health and the Ministry of Population Welfare". Refer to this document for additional information on procurement requisitions.

Preparing a Procurement Requisition (See Requisition Form SPF 1)

1. Prepare an initial description of requirements.
2. Estimate the value of the contraceptives. The estimate may be based on recent, similar contracts, market research, or an estimate by a technical specialist. Seek assistance from technical specialists within the parent Ministry or outside it, if required.
3. Obtain confirmation of the availability of funding for the requirement, through the signature of an authorised official on the Requisition Form. (This official will normally be the Head of the Finance Section in the Department concerned.)
4. Obtain approval to proceed with the procurement, through the signature of the budget holder, or other duly authorised official, on the Requisition Form. (The budget holder will normally be the relevant NHF Programme's manager duly authorised by the Accounting Officer).
5. Check the description of requirements, as far as possible, and attach it to the Requisition Form, if necessary.
6. If the Requisition has come from an end user, and has not been generated by the Procurement Unit itself, check the description of requirements with the end user and discuss any clarifications or changes required with the end user.
7. The officer who begins the procurement by initiating the requisition must sign the Requisition Form in order to certify that the contraceptives are required.

Note: Purchase Requisitions should NOT mix requirements. Separate requisitions should be used for different requirements.

Approvals Required

The requisition form SPF1 must be signed in three separate places by the appropriate official, to provide the following certifications:

- Availability of funding for the procurement requirement in the budget, based on the estimated value on the requisition form;
- Confirmation of the need for the goods, works or services listed on the requisition form; and
- Approval to proceed with the procurement process for those items.

Annexure 11. Procurement Records

CHECKLIST FOR PROCUREMENT RECORDS

Contract Number:	**Bid Number:**
Supplier Name:	**Bid Title:**
Date:	**Procurement Contact:**

	Included in file	Documentation type	Comments
1		Signed procurement requisition	
2		Product specifications	
3		Budget estimate	
4		Procurement plan and summary	
5		Bidders list	
6		Pre-qualification document	
7		Record of advertisement	
8		Bidding documents	
9		Bid security documentation	
10		Record of pre-bid conference	
11		Modifications to bidding documents	
12		Proposals from suppliers	
13		Record of bid opening	
14		Record of bid examination	
15		Bid review committee summary	
16		Award letter	
17		Performance guarantee documentation	
18		Signed contract	
19		Bidder notification	

20		Authorization for shipment	
21		Shipping documents	
22		Receiving report	
23		Miscellaneous correspondence	

Annexure 12. Table of Procurement Steps and Documents

Activity	Document
Module I - Planning and Preparation	
Complete procurement plan	Procurement Plan
Establish procurement record	Procurement Record Checklist
Assign bid packages and tasks	
Summarize procurement	Memorandum
Module II - Bidding Documents	
Obtain technical specifications	
Determine criteria for:	
a. Bid response	
b. Bidder qualification	
c. Contraceptive eligibility and conformity	
d. Bid evaluation	
Determine shipping terms	
Determine import procedures:	
a. Inspection/testing	
b. Documentation	
c. Licensing	
Determine payment terms	
Complie bid documents	Invitation for Bids, Instructions to Bidders, Bid Data Sheet, General Conditions of Contract, Special Conditions of Contract, Schedule of Requirements, Technical Specifications, Bid Form and Price Schedule, Qualification Statement
List of prospective bidders	Bidder’s List
Approval of bidding documents and fact sheet	

Activity	Document
Module III - Invitation for Bid	
Prepare Procurement Notice	
Post on GOP website, place in local & international newspapers, notify embassies, and/ or direct notifications	
Prepare records and safe keeping for bid securities	
Sell bidding documents	
Hold pre-bid conference (optional)	
Record and distribute minutes to all bidders	
Answer queries and distribute clarifcations to all bidders	
Module IV - Bid Opening & Selection	
Hold formal bid opening	
Record bids	Bid opening checklist
Confirm bid securities	
Bid evaluation process:	
a. Techincal evaluation	
b. Qualify technically responsive bidders	
c. Financial evaluation	Templates
d. Make recommendation	
Obtain relevant authority approval	
Module V - Award, Contract and Delivery	
Send award notice and contract form	Award notification
Obtain and confirm performance security	
Notify unsuccessful bidders	
Release bid securities	

Activity	Document
Arrange down payment	
Monitor contract execution	
Pre-shipment inspection	
Shipment and notification:	
a. Authorize shipment	
b. Advise clearing agent & stores	
c. Distribute shipping documents	
Customs clearance / delivery	
Receipt of goods:	
a. Obtain documents	
b. Forward invoices to Finance Unit	
Claims (if applicable)	
Closing the contract:	
a. Release performance security	
b. Mark file closed	

Annexure 13. Invitation for Bids (IFB)

[insert: name of country]

[insert: name of Ministry]

[insert: brief description of the Goods]

[insert: IFB title]

[insert: IFB number]

1. The *[insert name of implementing agency]* invites sealed bids from eligible bidders for *[insert brief description of goods or works to be procured]*.[1]

2. Bidding will be conducted through the international competitive bidding procedures and is open to all interested eligible bidders.

3. Interested eligible bidders may obtain further information from *[insert name of agency]* and inspect the bidding documents at the address given below [state address at end of document] from *[insert office hours]*.[2]

4. A complete set of bidding documents in *[insert name of language]* may be purchased by interested bidders on the submission of a written application to the address below *[state address at the end of document]* and upon payment of a nonrefundable fee[3] *[insert amount in local currency]*. The document will be sent by *[insert delivery procedure]*.[4]

5. Bids must be delivered to the address below *[state address at the end of document]* at or before *[insert time and date]*. If required, all bids must be accompanied by a bid security of *[insert amount in local currency or minimum percentage of bid price]* or an equivalent amount in a freely convertible currency.[5] Late bids will be rejected. Bids will be opened in the presence of the bidders' representatives who choose to attend at the address below *[state address at end of document]* at *[insert time and date]*.

[insert: name of office]

[insert: name of officer]

[insert: postal address] and/or

[insert: street address]

[insert: telephone number, indicate country and city code]

[insert: facsimile or cable number or e-mail address]

Footnotes to IFB

1. A brief description of the type(s) of goods or works should be provided, including quantities, location of project and other information necessary to enable potential bidders to decide whether or not to respond to the invitation. Bidding documents may require bidders to have specific experience or capabilities; such restrictions should also be included in this paragraph.
2. For example, 0900 to 1200 hours.
3. The fee, to defray printing and mailing/shipping costs, should be nominal.
4. The delivery procedure is usually airmail for overseas delivery and surface mail or courier for local delivery. If urgency or security dictates, courier services may be required for overseas delivery.
5. The amount of bid security, if required, should be stated as a fixed amount or as a minimum percentage of the bid price. Alternatively, if a bid security is not required (often the case in supply contracts), the paragraph should so state.

General Note

The content of the Invitation for Bids should be consistent with the Bid Data Sheet (BDS). In particular, the dates, times and place for bid submission and opening and the amount required for bid security in the IFB must be carefully checked to ensure consistency with the BDS. Also, the IFB could list key qualification criteria required for prospective Bidders to be responsive, as officially specified in the BDS (e.g., minimum financial capacity, the minimum number of years during which the prospective Bidder has manufactured and marketed similar goods).

Annexure 14: Evaluation and Qualification Criteria

Evaluation and qualification criteria are commonly used to help ensure that the purchaser selects a product and a manufacturer best qualified to meet the bid requirements. Standard evaluation and qualification criteria categories include:

1. Licensing and registration by appropriate authorities
2. Technical capacity and experience
3. Financial capability

Examples of evaluation and qualification criteria that can be used for these categories are listed below. The purchaser can select which criteria are most appropriate for the product to be procured. The purchaser can also include additional criteria as long as they are relevant and do not unduly restrict competition in an unfair manner.

Licensing and Registration

1. Product offered is registered with the required Pakistan Agency (if applicable). Provide product registration number or certificate.
2. Is product registered in country of origin and marketed in country of origin?
3. Is product registered for export only?
4. For products manufactured outside of Pakistan, does the manufacture have an local authorized representative licensed in Pakistan?

Technical Capacity and Experience

1. Does manufacturer have GMP certification? Provide a copy of certificate.
2. Total annual production capacity for the product the manufacturer is offering to supply.
3. Percent that the quantity of product offered in the bid is of the total annual production capacity for the product.
4. Number of years the manufacturer has been producing the product it is offering to supply.
5. Number of contracts of similar size for the product it is offering to supply that have been successfully completed with contact references for confirmation.

Financial Capability

1. Total annual average international sales turnover for each of the last three years as documented by audited financial statements.
2. Total annual average domestic sales turnover for each of the last three years as documented by audited financial statements

Annexure 15: Sample Format for Fact Sheet on Bidding Document

_____ Programme Fact Sheet on Bid

Contraceptives	(mention short description)
Quantity	(mention short description)
Estimated Cost	(mention Cost with currency)
Method of Procurement	(mention whether ICB or NCB or DC or otherwise)
Prior Review or not	(mention whether yes or no)
Requesting Agency	(end user)

Annexure 16. Standard Format for Advertisement for International Competive Bidding

(Name of Procuring Agency)

(Title/Name of Bid)

Procurement Number:_____

The (Name of Agency) has (allocated/received) funds *(if already received, state source of funds)* for the procurement of (insert title of the goods, works or services) and now invites sealed bids from eligible bidders for the supply of:

(Insert brief summary or list of the required goods)

(Insert brief narrative giving background information or further specification if necessary)

Bidding is open to all suppliers/contractors who can demonstrate (list criteria for eligibility)

Interested bidders may inspect the bidding document on the PPRA website www.ppra.org.pk or at the address below (insert hours between which the documents are available for inspection). Bidding documents may be purchased upon payment of a non-refundable fee of (insert fee amount, currency and payment format).

Bids must be delivered to the address below on or before (insert date and time of bid closing). All bids must be accompanied by:

- A bid security of not less than (insert fixed figure or percentage of the bid price);
- List all other required documents and samples where applicable.

Bids will be opened on (date) at (time), in the presence of bidders' representatives who choose to attend, at the address below. (If at a different address, state the address). Late bids will be rejected and returned unopened to bidders.

(Insert full name of procuring agency):	Name and/or title of person to contact:
Room Number:	Telephone Number:
Building Name:	Fax Number:
Street number and name (if appropriate):	Email address (if available):
Sector:	
City or Town, Postcode and Province:	

There will be no price negotiations with the lowest evaluated responsive bidders. Suppliers are, therefore, requested to submit their lowest and best prices with their bids.

Annexure 17. Sample Format for the Minutes of Pre-Bid Conference

Minutes of the Pre-Bid Conference on Bid Package No. (mention number)

1. Meeting date, place and time:
2. Bid Package No.:
3. Bidders represented: (mention names of bidders)
4. Discussion of the Conference:

Query and Reference	Reply/Clarification
(mention page no., paragraph no., section no., etc.)	(mention the exact reply/clarification)

Annexure 18. Sample Format for Forwarding Queries Raised in Pre-Bid Conference

Memo No……. Date

Government of Pakistan
Ministry of Population Welfare
(*mention address*)

To
Technical expert

Subject: Request for Clarification on query raised in pre-bid conference on

Bid package No. --- for (*mention name of goods)*
Ref: Pre-bid conference held on (*mention date*)

Dear Sir:

Queries raised in the pre-bid conference held on the subject bid package on (*mention date*) are mentioned in the attached copy of the minutes of the above-mentioned pre-bid conference for your clarification an necessary action.

We will appreciate your earliest response to the above. Please note that the bids are due for submission on (*mention bid submission date*).

Thanking you,

Copy for information to:

1. The user office.

Annexure 19. Sample Format for Replying to Queries Raised in Pre-Bid Conference

Memo No…… Date

Government of Pakistan
Ministry of Population Welfare
(*mention address*)

To

All Bidders

(*mention the names and addresses*)

Subject: Clarification on query raised in Pre-bid conference on Bid Package No. --- for (*mention name of goods*)

Ref: Pre-bid Conference held on (*mention date*)

Dear Sir:

Clarifications/replies to queries raised in the pre-bid conference on the subject bid package on (*mention date*) are mentioned for your information and necessary action.

Query and Reference	**Reply/Clarification**
(*mention page no., paragraph no., section no., etc.*)	(*mention the exact reply/clarification*)

Thanking you,

Copy for information to:

1. GOP
2. The User office

Annexure 20. Sample Format for Notification on Extension of Bid Submission Date

Sample format for Notification on extension of Bid Submission date for Bid Package No.*(mention no.)* for (*mention goods*)

Memo No…… Date

Government of Pakistan
Ministry of Population Welfare

(*mention address*)

To

M/S

(*All bidders who have purchased the Bid Package*)

Subject: Notification on extension of Bid submission date for

Bid package No. ---- for (*mention name of goods*)

In order to facilitate necessary actions on the reply/clarification to queries raised in the pre-bid conference held on the subject bid package on (*mention date*) the Bidding Document selling date and bid submission date are hereby extended as follows:

Event	Previous Date	Extended Date
Bidding Document	Upto (*mention date*)	Upto (*mention date*)
Bid submission date	(*mention date*)	(*mention date*)

We will appreciate your earliest response to the above. Please note that the bids are due for submission on (*mention bid submission date*).

Thanking you,

Copy for information to:1. NNRA.2. The User office.

Annexure 21. Standard Bid Evaluation Forms

Standard Bid Evaluation Forms

Section I. Bid Evaluation Standard Forms

Standard Cover Letter of Transmittal
Table 1. Identification
Table 2 Bidding Process
Table 3 Bid Submission and Opening
Table 4 Bid Prices (as Read Out)
Table 5 Preliminary Examination
Table 6 Corrections and Unconditional Discounts
Table 7 Exchange Rates
Table 8 Currency Conversion (Multiple Currencies)
Table 9 Currency Conversion (Single Currency)
Table 10 Additions, Adjustments and Priced Deviations
Table 11 Domestic Preference for Goods
Table 12 Domestic Preference for Works
Table 13 Proposed Contract Award

Annexure 22. Sample Format for Notification of Bid Opening

Sample format for notification of bid opening

Memo No…….. Date

Government of Pakistan

Ministry of Population Welfare

(*Mention Address*)

NOTIFICATION

Bids against Bid Package No. ---- will be opened on (mention date, time, and venue). Salient information about the package is given below.

Bid Package No.	Goods	Quantity	Estimated Cost	Method of Procurement
	Mention short description)	(Mention quantity with unit)	(Mention Cost with Currency)	(Mention whether ICB or NCB or DC or otherwise)

All members of the Bid Opening Committee are requested to kindly attend the meeting.

Copy for information and necessary action: all members of Bid Opening Committee.

Annexure 23. Record of Samples Received from Suppliers

Name of Procuring Agency **Form SPF 8**

RECORD OF SAMPLES RECEIVED FROM SUPPLIERS

Procurement Number					
PA	**Department/ Project**	**Financial Year**	**Sequence Number**	**Bid Number**	**Contract Number**

Subject of Procurement:	

S.N	Item	Supplier	Date Received	Test S.N.	Date Sent for Test	Date Returned	Remarks

S.N	Item	Supplier	Date Received	Test S.N.	Date Sent for Test	Date Returned	Remarks

Annexure 24. Bid Opening Checklist

Bid Opening Checklist

(To be filled out for each bid as it is read out)

Contract Reference: _____

Bid Opening Date: _____ Time: _____

Name of Bidder: _____

(a) Is outer envelope of bid sealed?

(b) Is bid form completed and signed?

(c) Expiration date of bid:

(d) Is documentary authority for signing enclosed?

(e) Amount of bid security (if required) _____ (state currency)

(f) Describe any "Substitution," "Withdrawal," or "Modification" submitted

(g) Describe any alternative bid made:

(h) Describe any discounts or modifications offered:

(i) Name of bidder or representative present:

(j) Total bid price: _____ (List currencies and amounts or percentages, if bid is for a package of contracts, the price for each lot or item should be read out.)

Signature of responsible official: _____

Date: _____

Annexure 25. Record of Bid Opening

RECORD OF BID OPENING

Name of Project/Contract: _____

Invitation for Bid No.: _____

Date: _____

Time: _____

	Bidder's Name and Address	Local Agent's Name and Address	Bid Currency	Total Bid Price	Modifications or Comments (Discounts, Withdrawals, Missing Bid Security, etc.)
1.					
2.					
3.					
Etc.					

BIDDERS PRESENT

	Name	Company	Signature
1.			
2.			
Etc.			

MEMBERS OF BID/TENDER OPENING COMMITTEE

	Name	Signature
1.		
2.		
Etc.		

Annexure 26: Guidance Notes on Bid Opening

(From Manual of Procurement Policies and Standard Operating Procedures for the NHF Programmes of the Ministry of Health and the Ministry of Population Welfare, Government of Pakistan. SOP 19)

Guidance Notes on Bid Opening

1. Prepare the room prior to the tender opening time. Staff must ensure that appropriate resources, both physical and human, are available to manage the tender opening efficiently.
2. The person chairing the opening must ensure that all staff involved understand their respective roles in the procedure.
3. The chairperson of the Bid Opening Committee should welcome bidders to the opening and request them all to sign the record of attendance. He/she should briefly explain the procedure which will be followed, which is normally opening of the sealed tender box, counting of all tenders, opening of tenders, reading out and recording of information by the PA, opportunity for bidders to ask questions, closing of meeting and removal of tenders for safe-keeping and evaluation.
4. The seal of the Tender Box should be shown to those present at the Bid Opening Committee meeting and then broken.
5. The tender box should be opened and all tenders removed and counted.
6. First, envelopes marked "Withdrawal" should be opened one at a time. These should be read out and the envelope containing the corresponding tender located and returned to the bidder unopened. The withdrawal must be noted on the record of the tender opening.

   N.B. "Withdrawals" refer to bidders who, having submitted a tender well in advance, wish to withdraw their bids and do not wish to have their bids considered.
7. Next, envelopes marked "Modification" should be opened one at a time and the envelope containing the corresponding tender located and opened. Details of the modified tender should be read out and recorded, ensuring that the details relate to the modified, not the original, tender. Both the original tender and modification should be stamped on key pages and signed or initialled by the chairperson of the opening, and by all members of the Bid Opening Committee, if demanded.

   N.B. "Modifications" refer to bidders who, having submitted a first tender well in advance, have then modified the terms of their tender (e.g., as a result of an unexpected change in the price of a key manufacturing input) and have placed another envelope marked "Modification" into the Tender Box before the date and time of Bid Opening.

8. After counting the remaining Tenders, each Tender Envelope should be marked with a serial number starting with the number "1".
9. List the tenders in numerical order. The tenders should then be opened, one at a time, and the relevant details read out and recorded as a line item against each serial number, using the Record of Bid Opening Form.
10. Each tender should be stamped on key pages and signed or initialled by the chairperson of the opening, and the pages should also be counter-signed by all members of the Bid Opening Committee (BOC). Each tender should also be marked with a number (1, 2, 3, etc.), corresponding to its number on the Bid Opening record. With the exception of late tenders, the BOC must not make any comments regarding the acceptance or rejection of any tender. Any missing or incorrect documents should be noted in the record of bid opening, but not commented on.
11. When all tenders received on time have been opened, read out and recorded.

    Information to be read out should be as stated in the bidding document. This must include at least:

    - the name and address of each bidder;
    - the total price of each tender, stating the currency and amount;
    - each unit price quoted (in addition to the total price or lot prices to be read out) stating the currency and amount.

    It may also include:

    - the presence or absence of a Bid Security, and the form and amount of the Bid Security, where one was requested in the bidding document;
    - any other details stated in the bidding document.

    No additional information concerning any tender should be read out, other than that required by the bidding document.
12. The chairperson of the BOC should close the Bid Opening meeting, reminding bidders that they must not seek to influence the evaluation and that the Tender Evaluation Report will be announced in due course in accordance with Rule 35 Announcement of Evaluation Reports contained in PPR 2004.
13. Copies of the tender opening record should be distributed to bidders on request. The original record should be added to the procurement file.
14. All tenders should be immediately taken to a place of safe keeping, until the evaluation committee is ready to meet. Any tender securities must also be kept securely.

Annexure 27. Sample Format for Confirmation of Bid Security

Sample Format for Confirmation of Bid Security

Memo No. Date

Government of Pakistan
Ministry of Population Welfare
(*Mention address*)

Manager, Issuing Bank

(*Mention name and address of the bank branch as evident from the Bid Security*)

Subject: Bank Guarantee/Pay Order/Cashier's Cheque (*mention no. & date*)

You are requested to kindly confirm issuance of the above-mentioned Bank Guarantee/Pay Order/Cashier's Cheque (*mention no. & date*) submitted to us by (*mention the bidder's name and address*) against bid package no. (*mention no.*).

Salient information about the instrument is given below.

Type of Guarantee	Issued in favour of	Amount and currency	Validity
(mention whether it is a Bank Guarantee or Pay Order or Otherwise)	*(mention bidder's name)*	*(mention amount and currency)*	*(mention period)*

Your early response will be highly appreciated.

Annexure 28. Table 1. Identification

1.1	Programme Name	_____
1.2	Funding number	_____
1.3	Date of effectiveness	_____
1.4	Closing date	
(a)	original	_____
(b)	revised	_____
1.5	Name of project	_____
1.6	Purchaser (or Employer)	
(a)	name	_____
(b)	address	_____
1.7	Contract number (identification)	_____
1.8	Contract description	_____
1.9	Cost estimate[1]	_____
1.10	Method of procurement (check one)	ICB _____ LIB _____ Other _____
1.11	Prior review required[2]	Yes _____ No _____
1.12	Domestic preference allowed	Yes _____ No _____
1.13	Fixed price contract	Yes _____ No _____

[1] Cite source and date if other than Staff Appraisal Report.

[2] If response is “no,” items 2.2(b), 2.4(b), and 2.6(b) in Table 2 may be left blank.

Annexure 29. Table 2. Bidding Process

2.1	Specific procurement notice	
	(a) name of national newspaper	_____
	(b) issue date	_____
	(c) name of international publication	_____
	(d) issue date	_____
	(e) PPRA website date	_____
2.2	Standard Bidding Document	
	(a) title, publication date	_____
	(b) date of issue to bidders	_____
2.3	Number of firms issued documents	_____
2.4	Amendments to documents, if any	
	(a) list all issue dates	1. _____ 2. _____ 3. _____
		1. _____ 2. _____ 3. _____
2.5	Date of pre-bid conference, if any	_____
2.6	Date minutes of conference sent to bidders	_____

Annexure 30. Table 3. Bid Submission and Opening

3.1	Bid submission deadline	
(a)	original date, time	_____
(b)	extensions, if any	_____
3.2	Bid opening date, time	_____
3.3	Record of bid opening	_____
3.4	Number of bids submitted	_____
3.5	Bid validity period (days or weeks)	
(a)	originally specified	_____
(b)	extensions, if any	_____

Annexure 31. Table 4. Bid Prices (as Read Out)

Bidder Identification			Read-out Bid Price(s)[1]		Modifications or Comments[2]
Name *(a)*	City/State or Province *(b)*	Country *(c)*	Currency(ies) *(d)*	Amount(s) or % *(e)*	*(f)*
etc.					

[1] For single currency option (see Annex I, para. 6(d)(ii)), secondary currencies are expressed in column e as a percentage of the total bid price.

[2] Describe any modifications to the read-out bid, such as discounts offered, withdrawals and alternative bids. Note also the absence of any required bid security or other critical items.

Annexure 32. Table 5. Preliminary Examination

Bidder *(a)*	Verification *(b)*	Eligibility *(c)*	Bid Security *(d)*	Completeness of Bid *(e)*	Substantial Responsiveness *(f)*	Acceptance for Detailed Examination *(g)*
etc.						

Annexure 33. Technical Evaluation Sub-Schedule for Table 5

Technical Evaluation Sub-Schedule for Table 5 (column f)

Name of Bidder_____ Contract No._____

Name of Item: _____

	Specification per Bidding Document	Remarks (acceptable, unacceptable, - if unacceptable, provide reasons)
1.		
2.		
3.		
4.		
5.		

Offered Product's Brand Name: _____

Overall Comments:

(If product mentioned above is other than what was specified in the bidding documents, please state whether or not the substituted product offers substantial equivalence in critical performance parameters or in other requirements.)

Signature of technical expert_____

Date_____

Annexure 34. Summary of Technical Evaluation

Name of Procuring Agency

Form SPF 4
Page __of ___

Procurement Number					
Agency	**Department/ Project**	**Financial Year**	**Sequence Number**	**Bid Number**	**Contract Number**

No.	**Bidder**	**Technical Compliance**	**Comments** (Reasons for non compliance)
1		C/NC	
2		C/NC	
3		C/NC	
4		C/NC	
5		C/NC	
6		C/NC	

KEY: **C** DENOTES COMPLIANT **NC** DENOTES NON-COMPLIANT

This examination eliminated [number] companies, [Names of Companies].

List names of companies eliminated on separate sheet(s).

Attach Combined Technical Specification and Compliance Sheets for each Quotation/ Tender if technical evaluation is complex.

Annexure 35. Verification Checklist for SBEF Table 5 (column b)

Verification Checklist for SBEF Table 5 (column b)

Bidder's Name_____Contract Number_____

1. Bid Form and Price Schedule filled in and duly signed? (yes/no)
2. Bid validity period conforms to the requirement in the bidding documents? (yes/no)
3. If the bidder is a joint venture, Joint Venture agreement provided? (yes/no/not applicable)
4. If the bidder is not the manufacturer, whether bidder provided Manufacturer's confirmation to warranty obligations? (yes/no/net applicable)
5. If the bid has been submitted by an agent, whether the Manufacturer's Authorization to submit the bid is provided? (yes/no/not applicable)

Annexure 36. Eligibility Checklist for SBEF Table 5 (column c)

Eligibility Checklist for SBEF Table 5 (column c)

Bidder's Name_____ Contract No._____

1. Has this bidder been pre-qualified? (yes/no/not applicable)
2. Is bidder a national of an eligible source country? (yes/no)
3. If bid is from a joint venture, are all partners nationals of an eligible source country? (yes/no/not applicable)
4. If bid is from a joint venture, is the joint venture registered in an eligible source country? (yes/no/not applicable)
5. Do the goods and/or services offered originate from eligible source countries? (yes/no)
6. If the bidder is a publicly owned enterprise in Pakistan, is the bidder legally and financially autonomous and operating under commercial law? (yes/no/not applicable)

Annexure 37. Bid Security Checklist for SBEF Table 5 (column d)

Bid Security Checklist for SBEF Table 5 (column d)

Name of Bidder_____ Contract No._____

1. Is bid accompanied by bid security? (yes/no)
2. Does the amount of the bid security conform to the amount required in the bidding documents? (yes/no)
3. Does the period of the bid security conform to the period required in the bidding documents? (yes/no)
4. If bid security is issued as a bank guarantee, is it consistent with the wording of the bid security form provided in the bidding document? (yes/no/ not applicable)
5. If the bid is submitted by a joint venture, is the bid security in the name of all of partners of the joint venture? (yes/no/not applicable)

Annexure 38. Completeness of Bid Checklist for SBEF Table 5 (column e)

Completeness of Bid Checklist for SBEF Table 5 (column e)

Bidder's Name_____ Contract No._____

1. Does the Bidder offer all of the required items? (yes/no)
2. Does the Bidder offer full quantities of the required items? (yes/no)
3. Has the Bidder made any additions, deletions or other changes to the original bidding documents? (yes/no)
4. Has the Bidder initialed any erasures, additions, deletions or other changes to the original bidding documents? (yes/no)
5. Are all pages of the bidding document and the bid included in the submission? (yes/no)
6. Are all of the required documents and attachments included with the bid? (yes/no) (If no, list missing items.)

Annexure 39. Commercial Responsiveness Sub-Schedule for SBEF Table 5 (column f)

Commercial Responsiveness Sub-Schedule for SBEF Table 5 (column f)

Bidder's Name_____ Contract No._____

1. Does the bidder ask for price adjustments when a fixed price bid was invited? (yes/no)

2. Does the bidder offer an alternative design in the bid?(yes/no)

3. What is the completion/delivery time offered in the bid?

4. Does the completion/delivery time offered in the bid conform to the Schedule of Requirements in the Bidding Documents? (yes/no)

5. Is any sub-contracting mentioned in the bid? (yes/no)

6. Does the bidder agree to bear the responsibilities and liabilities allocated in the bidding documents, such as performance securities, insurance coverage, etc.? (yes/no) If no, provide details.

7. Does the bidder agree to applicable law, taxes and duties and dispute resolution procedures specified in the bidding documents? (yes/no) If no, provide details.

Annexure 40. Table 6. Corrections and Unconditional Discounts

Bidder	Read-out Bid Price(s)		Corrections		Corrected Bid Price(s)	Unconditional Discounts[2]		Corrected/ Discounted Bid Price(s)
	Currency(ies)	Amount(s)	Computational Errors[1]	Provisional Sums		Percent	Amount(s)	
(a)	*(b)*	*(c)*	*(d)*	*(e)*	*(f) = (c) + (d) - (e)*	*(g)*	*(h)*	*(i) = (f) – (h)*
etc.								

Note: Only bids accepted for preliminary examination (Table 5, column *g*) should be included in this and subsequent tables. Columns *a*, *b*, and *c* are from Table 4 (columns *a*, *d*, and *e*, respectively).

[1] Corrections in column *d* may be positive or negative.

[2] If the discount is offered as a percent, column *h* is normally the product of the amounts in columns *f* and *g*. If the discount is provided as an amount, it is entered directly in column *h*. A price increase is a negative discount.

Annexure 41. Table 7. Exchange Rates

Currency Used for Bid Evaluation: _____

Effective Date of Exchange Rate: _____

Authority or Publication Specified for Exchange Rate: _____

Note: Attach copy of exchange rates provided by specified authority or publication.

Annexure 42. Table 8. Currency Conversion (Multiple Currencies)

Specify Evaluation Currency: _____

Bidder *(a)*	Currency(ies) of Bid *(b)*	Corrected/ Discounted Bid Price(s) *(c)*	Applicable	Evaluation Currency	
			Exchange Rate(s)[1] *(d)*	Bid Price(s) *(e) = (c) x (d)*	Total Bid Price[2] *(f)*
etc.					

Note: This table is to be used for SBDG and Option B of SBDLW. Columns a, b and c are from Table 6, columns a, b and i.

[1] Column d is from Table 7. 2. Column f is the sum of bid prices in column e for each bidder.

Annexure 43. Table 10. Additions, Adjustments and Priced Deviations

Specify Evaluation Currency:

Bidder (a)	Corrected/Discounted Bid Price[1] (b)	Additions[2] (c)	Adjustments[2] (d)	Priced Deviations[2] (e)	Total Price (f) = (b) + (c) + (d) + (e)
etc.					

Note: See Paragraph G.4.1 in Module IV for an explanation of the term "Additions".

[1] Column b is from Table 8, column f .

[2] Each insertion in columns c, d, or e should be footnoted and explained in adequate detail, accompanied by calculations.

Annexure 44. Table 11. Domestic Preference for Goods

Specify Evaluation Currency: _____

Bidder	Domestic Preference Group[1]	Total Price[2]	Exclusions for Preference[3]	Revised Total	Prevailing Tariff (%)[4]	Domestic Preference (%)[5]	Preference Price[6]	Total Comparison Price
(a)	*(b)*	*(c)*	*(d)*	*(e) = (c) – (d)*	*(f)*	*(g)*	*(h)*	*(i) = (c) + (h)*
etc.								

[1] Column *b* refers to Groups A, B, or C, as indicated by bidder, subject to verification by Borrower.

[2] Column *c* is from Table 10, column *f*. If the lowest total price is from a Group A or Group B bidder, it is the lowest evaluated bidder, and the remainder of the table need not be filled out. Columns *d* through *h* need to be filled out only for Group C bids.

[3] Column *d* is the sum of costs in columns *d* and *e* from Table 10 plus other costs incurred within the Borrower's country. Footnotes should be provided to explain the significant components of column *d*.

[4] Column *f* is the sum of duties and import taxes on the particular items or group of similar items as a percent of the CIF or CIP price.

[5] Column *g* will be the smaller of 15 percent or the prevailing tariff in column *f*.

[6] Column *h* for Group A bidders is zero. Group B bids at this stage should no longer be compared. For Group C bidders, column *h* is the product of columns *e* and *g*.

Annexure 45. Ranking Worksheet

Ranking Worksheet

Contract No._____

Bid Opening Date _____

Bidder	Total Bid Price	Ranking*

*Prior to cross discount calculations

Annexure 46. Cross Discount Worksheet

Cross Discount Worksheet					
Bidder	Bid Packages grouped by bidder for discount	%Discount Offered	Discounted Price of Bid Packages (b) x (c)	Prices offered by the lowest evaluated bidders for Column (b) packages	Comparison Column d total and Column e totals
(a)	(b)	(c)	(d)	(e)	(f)
	1.				
	2.				
	3.				
			(total)	1.	
				2.	
				3.	
				(total)	

Cross Discounts

These are conditional discounts the Bidder offers the Purchaser when more than one contract or lot could be awarded to the same Bidder. The Bid Evaluation Committee must select the best combination of awards on the basis of least overall cost of the total contract package. Bid evaluation in such cases can be complicated, with many variations.

The Cross Discount worksheet shows an example of basic information and calculations needed to determine whether it would be less expensive to purchase a group of bid packages individually from each of the lowest evaluated bidders, or as a group of bid packages from one bidder who offers a discount applied to the total.

Instructions for completing Cross discount Worksheet:

Column a (first line): Enter name of bidder offering a Conditional Discount.

Column b (first line): List the bid packages that would be discounted by bidder in column a if all packages in the group were awarded to him. Include the package number and the price without discount.

Column c (first line): Enter the discount offered by the bidder (usually a percentage).

Column d: Apply the discount in column c to each bid package price noted in column b to find a discounted price for each bid package; next, calculate the sum of the discounted bid package prices and enter that amount on the first line of column d.

Column e: Starting on the second line, list the lowest evaluated bidder for each separate bid package in column a, the corresponding bid package number in column b and the bid prices in column e; next, calculate the sum of the lowest evaluated bid prices and enter the total on the first line of column e.

Column f: Indicate the lower of column d and e; include remarks.

Annexure 47. Sample Worksheet: Bidder's Qualification Criteria

A. Manufacturer has adequate production capability

1. Annual capacity for production of subject goods is at least three times the quantity specified in the Schedule of Requirements for this bid.
2. Installed manufacturing capacity for subject goods less existing contracts for delivery of subject goods exceeds quantities specified in Schedule of Requirements for the same period.

B. Bidder has verifiable business and financial stability

1. Manufacturer's average annual sales value over the past three years is at least five times the estimated contract value (requires calculation).
2. Manufacturer has produced the specific goods subject of bidding for at least two years, and for similar goods for at least five years.
3. Agent, if applicable, has marketed specific or similar goods for at least three years.
4. Manufacturer is licensed or otherwise registered with tax authorities for doing business in the country of domicile.
5. Agent, if applicable, is licensed or otherwise registered with tax authorities for doing business in Pakistan.
6. Manufacturer has maintained a business bank account for at least five years.
7. Agent, if applicable, has maintained a business bank account for at least three years.

Annexure 47. Sample Worksheet: Bidder's Qualification Criteria

C. Manufacturer has verifiable technical capability

1. Manufacturer of goods has a valid license issued by the competent regulatory authority in the country of manufacture.
2. Manufacturer of goods has received satisfactory GMP inspection in line with the WHO certification scheme on pharmaceuticals moving in International Commerce from regulatory authority in the country of manufacture within the two years prior to bid.

or….

3. Manufacturer has been certified by the competent authority of a member country of the Pharmaceuticals Inspection Convention and has demonstrated compliance with the quality standards during the two years prior to bid.
4. Manufacturer has on-site quality control, quality assurance testing facilities.

D. Bidder has verifiable history of successful performance

1. Number of similar contracts completed by bidder is not less than three and not more than five (normally four) within the last five years, depending on the size and complexity of the subject contract.
2. Reference check reveals satisfactory business dealings with at least five similar customers.
3. Reference check with at least five similar customers reveals satisfactory quality of products supplied.

Annexure 48. Bid Evaluation Report

(From Manual of Procurement Policies and Standard Operating Procedures for the NHF Programmes of the Ministry of Health and the Ministry of Population Welfare, Government of Pakistan. SPF Form 4)

Name of Procuring Agency

SPF Form 4
Page __of
___

BID EVALUATION REPORT

Procurement Number					
PA	**Department/ Project**	**Financial Year**	**Sequence Number**	**Bid Number**	**Contract Number**

Introduction
The requirement is for the procurement of [subject of procurement].

The procurement method used and approved by the RA was [Open Tender/ Limited Tender/ Request for Quotations/Direct Procurement].

Details of Invitation
The bidding documents were approved by the RA on [date]. The announcement was advertised on the [date] in [name of publications]. A list of bidders purchasing the Bidding Documents is attached.

{Or for Limited Tender/RFQ/ or following Pre-qualification for this Tender}

The bidding documents were approved by the RA on [date]. The shortlist of bidders was selected by the following method [explain method of selection].

Other Bidding Information
[List any other information on the bidding process, including any Pre-Bid Meeting, clarifications requested, or extensions of bidding period, and list and attach the appropriate records.]

Bid Closing
Bids were closed on [date] at [time] at [location].

Details of Bid Opening/Quotation Opening

Bids were opened in public at [location] by the Bid Opening Committee on [date] at [time]. Copies of the Record of Bid Opening, the Register of Attendance, and the Record of Samples Received are attached.

[Explain any important issues that arose during the bid opening procedures.]

The sealed quotations were opened at [location] by the Bid Opening Committee on [date] at [time]. Copies of the Record of Bid Opening, the Register of Attendance, and the Record of Samples Received are attached.

Evaluation Procedures

The Technical (Evaluation) Committee consisted of the following officials:

[Name]	[Position]	(Chairman of Evaluation Committee)
[Name]	[Position]	
[Name]	[Position]	
[Name]	[Position]	

Evaluation Methodology

The evaluation method specified in the bidding documents was the lowest priced bid (Least Cost Selection) of the technically compliant and responsive bids.

[Explain important evaluation criteria such as evaluated price adjustments (e.g., for delays) to be used in determining the best evaluated bid, acceptable deviations from the confidential price estimate, or other criteria as specified in the bidding documents.]

Preliminary Examination of Bids

Bids were examined to determine the:

- submission of the required bid security:
- commercial responsiveness of each bid to the Invitation; and
- eligibility and qualifications of the bidder.

The results of this preliminary examination are given in Table 1 attached.

[Explain why any bids were declared non-responsive and rejected during the preliminary examination.]

Technical Evaluation

i. Technical evaluation determined the compliance of each responsive bid to the technical specification issued in the bidding documents.

ii. {Samples submitted were inspected and confirmed to be acceptable.}

iii. Technical evaluation was conducted on a pass/fail basis only. Only bids that passed both the preliminary responsiveness and technical compliance tests were considered for financial evaluation.

The evaluation of the technical specifications of all bids is summarised in Table 2.

[Give a brief description of the results of the Technical Evaluation, with detailed justification as to why any bids were declared non-compliant.]

Financial evaluation (of technically compliant and responsive bids)
All responsive and technically compliant bids were examined and tabulated in Table 3 to:

i. record the submitted bid prices;
ii. correct for any omissions or arithmetic mistakes;
iii. convert the bid prices to Pakistani Rupees (if necessary); and
iv. adjust the bid prices for criteria specified in the bidding document (such as delayed delivery penalties) to arrive at the evaluated bid price for comparison;
v. rank bids on the basis of the lowest evaluated price.

[Describe for each bid any corrections, errors in calculations, penalties added to the bid price for evaluation purposes and conversion to a common currency if necessary.]

Qualification (when no pre-qualification procedure was used)
The Qualification as per Rule 17 is subject to reasons to be recorded and may be applied whether Pre-Qualification under Rule 15 has been done or not.

The best ranked bid submitted by [Name of Company] was subjected to Qualification examination covering (add/delete as applicable):

i. experience and performance on similar contracts;
ii. equipment and manufacturing/construction facilities
iii. qualifications and experience of personnel;
iv. financial position;
v. local facilities and representation;
vi. current capacity available;

[Record any constraints or limitations, and accept or reject (with full justifications) the bidder.]

{If the bidder is rejected, repeat the Qualification test for the next ranked bidder.}

[Name of Company] is confirmed to have passed the Qualification requirements.

The original estimated market price of the procurement was [insert amount]

Recommendation

On the basis of the evaluation criteria stated in the bidding document, it is recommended that the award be made to [Name of Company] for a total contract value of [currency and amount] for the procurement of [list all items that the award relates to]. {Or recommend negotiations with the recommended Company and state the purpose of negotiations.}

Signed by the Technical (Evaluation) Committee:

Signature:……..Name:…….

Signature:……..Name:…….

Signature:……..Name:…….

Date:……(DD/MM/YY)

Attachments: (where applicable)

List of Bidders who purchased or received the bidding documents.

Record of Bid Opening

Record of Samples Received

Bid Opening Attendance List.

Evidence of Exchange Rates used for conversion to Pakistani Rupees

TABLE 2 – SUMMARY OF TECHNICAL EVALUATION

(ONLY BIDS THAT ARE RESPONSIVE)

Form SPF 4

Procurement Number					
Agency	**Department/ Project**	**Financial Year**	**Sequence Number**	**Bid Number**	**Contract Number**

No.	**Bidder**	**Technical Compliance**	**Comments** (Reasons for non compliance)
1		C/NC	
2		C/NC	
3		C/NC	
4		C/NC	
5		C/NC	
6		C/NC	

KEY: **C** DENOTES COMPLIANT **NC** DENOTES NON-COMPLIANT

This examination eliminated [number] bidders, [Names of Bidders].

List names of bidders eliminated on separate sheet(s).

Attach Combined Technical Specification and Compliance Sheets for each Quotation/ Tender if technical evaluation is complex.

TABLE 3 – SUMMARY OF PRICE EVALUATION
(ONLY BIDS THAT ARE RESPONSIVE AND TECHNICALLY COMPLIANT)

Form SPF 4

Procurement Number					
PA	Department/ Project	Financial Year	Sequence Number	Bid Number	Contract Number

No.	Bidder	Amount of Bid and Currency	Corrections to Bid Price	Exchange rate	Amount in Pakistani Rs.	Adjustments to Bid Price	Evaluated Bid Price	Rank
1								
2								
3								
4								
5								
6								

Annexure 49: Request for Evaluation Report Approval

(From Manual of Procurement Policies and Standard Operating Procedures for the NHF Programmes of the Ministry of Health and the Ministry of Population Welfare, Government of Pakistan.)

Name of Procuring Agency **Form SPF 2**

SUBMISSION TO RELEVANT AUTHORITY

REQUEST FOR APPROVAL OF EVALUATION REPORT

Procurement Number					
Entity	**Department/ Project**	**Financial Year**	**Sequence Number**	**Bid Number**	**Contract Number**

Subject of procurement:	

No.	Bidder	Amount of Bid and Currency
1	Type of evaluation Report (Technical only or Combined Financial and Technical)	
2	Have negotiations been held with the recommended Bidder or other bidders – if yes give details	
3	Name and address of Supplier/Contractor recommended for contract award	
4	Currency and total amount of recommended contract award	
5	Any other relevant information	

Documents Attached: *(List any other documents or delete if not applicable)*

1. Evaluation Report for Goods
2. Record of Negotiations (if applicable)
3. Copies of all Bids submitted

Related Documents Submitted Previously: *(Available for reference from the Secretariat to the Tender Committee)*

1. Approved Bidding Document

Previous Submission: *(Section letter and title)*		**Date Approved:**	

The information contained in this form and the attached documents is complete, true and accurate and in accordance with the Ministry Procurement Manual and Standard Bidding Documents.

Signature: _____ Name: _____

Position: _____ Date: _____

Responsible Officer *(DD/MM/YY)*

Annexure 50: Recommendation for Contract Award

Name of Procuring Agency **Form SPF 2**

SUBMISSION TO RELEVANT AUTHORITY
RECOMMENDATION FOR CONTRACT AWARD

Procurement Number					
Entity	**Department/ Project**	**Financial Year**	**Sequence Number**	**Bid Number**	**Contract Number**

Submission information		
1	**Name and address of Supplier/Contractor**	
2	**Total value of Contract**	
3	**Proposed date of contract signature**	
3	**Any other relevant information**	

Documents Attached: *(List any other documents or delete if not applicable)*

1. Draft Contract
2. Draft Notice of Award

Related Documents Submitted Previously: *(Available for reference from the Secretariat to the Tender Committee)*

1. Approved Bidding Document
2. Approved Evaluation Report

Previous Submission: *(Section letter and title)*		**Date Approved:**	

The information contained in this form and the attached documents is complete, true and accurate and in accordance with the Ministry Procurement Manual and Standard Bidding Documents.

Signature: _____ Name: _____

Position: _____ Date: _____
Responsible Officer *(DD/MM/YY)*

Annexure 51: Contract Award Proforma I

PUBLIC PROCUREMENT REGULATORY AUTHORITY (PPRA)

To Be Filled and Uploaded on PPRA Website in Respect of All Public Contracts of Works, Services and Goods Worth Rs 50 Million or More

NAME OF THE ORGANIZATION/DEPT._____

FEDERAL / PROVINCIAL GOVT._____

TITLE OF CONTRACT _____

TENDER NUMBER _____

BRIEF DESCRIPTION OF CONTRACT _____

_____

_____

_____

TENDER VALUE_____

ESTIMATED COMPLETION PERIOD_____

WAS THE PROCUREMENT INCLUDED IN ANNUAL PROCUREMENT PLAN?
_____ Yes/No

ADVERTISEMENT:

(i) PPRA Website_____Yes/No

(Federal Agencies) (If yes give date and PPRA's tender number)

(ii) Newspapers_____Yes/No

(If yes give names of newspapers and dates)

TENDER OPENED ON (DATE & TIME)_____

NATURE OF PURCHASE_____Local/International

EXTENSION IN DUE DATE (If any)_____ Yes/No

* NUMBER OF TENDER DOCUMENTS SOLD_____

(Attach list of Buyers)

WHETHER QUALIFICATION CRITERIA WAS INCLUDED IN BIDDING/TENDER DOCUMENTS? _____Yes / No

(If yes enclose a copy)

WAS EVALUATION CRITERIA INCLUDED IN BIDDING/TENDER DOCUMENTS? _____Yes / No

(If yes enclose a copy)

WHICH METHOD OF PROCUREMENT WAS USED:- (Tick one)

(a) SINGLE STAGE – ONE ENVELOPE PROCEDURE _____
(b) SINGLE STAGE – ONE ENVELOPE PROCEDURE _____
(c) TWO STAGE BIDDING PROCEDURE_____
(d) TWO STAGE - TWO ENVELOPE PROCEDURE_____

– PLEASE SPECIFY IF ANY OTHER METHOD OF PROCUREMENT WAS ADOPTED WITH BRIEF REASONS (i.e., EMERGENCY, DIRECT CONTRACTING, NEGOTIATED TENDERING, ETC.)
– WHO IS THE APPROVING AUTHORITY?_____

WHETHER APPROVAL OF COMPETENT AUTHORITY WAS OBTAINED FOR USING A METHOD OTHER THAN OPEN COMPETITIVE BIDDING?

NUMBER OF BIDS RECEIVED _____

WAS THE SUCCESSFUL BIDDER THE LOWEST BIDDER?_____Yes/No

WAS THE INTEGRITY PACT SIGNED? _____Yes/No

Annexure 52: Contract Award Proforma II

PUBLIC PROCUREMENT REGULATORY AUTHORITY (PPRA)

To Be Filled and Uploaded on PPRA Website in Respect of All Public Contracts of Works, Services & Goods Worth Rs 50 Million or More

NUMBER OF BIDDERS PRESENT AT THE TIME OF OPENING OF BIDS

NAME AND ADDRESS OF THE SUCCESSFUL BIDDER

RANKING OF SUCCESSFUL BIDDER IN EVALUATION REPORT
(i.e., 1st, 2nd, 3rd EVALUATED BID)

NEED ANALYSIS (Why the procurement was necessary?)

IN CASE EXTENSION WAS MADE IN RESPONSE TIME, WHAT WERE THE REASONS (Briefly describe)

Annexure 53: Case Study

International Competitive Procurement of Oral Contraceptive

General information

This case study is provided to illustrate how to use the bid evaluation forms (Annexures 33-45) in evaluating bids received from manufacturers/suppliers. In this case study, the bids have been opened and a preliminary examination has been conducted which determined that all bids are eligible for technical evaluation. The case study will not be able to go into the level of detail that a full bid evaluation requires. Rather, it is intended to represent an overview of the overall approach for using the evaluation forms to conduct a bid evaluation. For example, instead of providing complete simulated bids from each supplier, a summary table that lists key information that was theoretically obtained from reviewing the manufacturers' bids is provided at the end of this case study. Information from this summary table will be used to help complete the bid evaluation forms.

There are several steps to be conducted in a bid evaluation and this case study will follow the process outlined in Module IV of this manual.

Note: This is a hypothetical case study and the names of the manufacturers are fictional and do not represent any actual manufacturer or supplier. The information provided in the case study does not represent actual manufacturer or supplier information.

Background

On March 10, 2010, the Ministry of Population Welfare issued International Competitive Bid number 7 for the oral contraceptive tablet norgestrel and ethinyl estradiol in 28 day cycle packages. The request was for 800,000 oral contraceptive packages (cycles) split equally into two separate deliveries: 400,000 cycles delivered to Karachi by September 1, 2010, and 400,000 cycles delivered to Karachi on December 1, 2010. In addition to the technical specifications, the invitation to bid package included Instructions to Bidders, Bid Data Sheet, General Conditions of Contract, Special Conditions of Contract, Schedule of Requirements and sample bid forms.

Bids were received from three suppliers. The bids were opened April 10, 2010, at the scheduled time and the key information was read aloud to those attending the bid opening. Information from the bid opening was recorded on a bid opening sheet and, following a preliminary exam, all three proposals were accepted for technical evaluation.

Bid Evaluation

In an actual bid evaluation, it is important for the evaluator to thoroughly review the original Bidding Documents to fully understand the technical specification requirements, the Schedule of Requirements, and any special requirements noted in the Bid Data Sheet and Special Conditions of Contract. As noted in the general information section above, for

this case study complete manufacturer bids are not provided. Instead key information from each manufacturer's bid is presented in the Summary of Bid Information Table.

Technical evaluation

Following preliminary examination, the next step in the evaluation process is to perform a technical evaluation to ensure the contraceptive offered meets the key technical specification requirements. This is usually performed by a technical expert or a technical evaluation committee. The committee completes the Technical Evaluation Sub-schedule for Table 5 by listing the key technical specification requirements on the sub-schedule. The committee then reviews each manufacturer's bid to confirm if the contraceptive offered meets the specification requirements.

In this case study, a few key technical specification requirements that were listed in the Summary of Bid Information Table have been placed on the Technical Evaluation sub-schedule. In an actual technical evaluation, there will be more technical specification requirements to consider for the sub-schedule. In our case study, the technical evaluation has reviewed the bids from Alhambra Pharmaceuticals, Dalian Medicines and Garhiem Health Care and has found all to be compliant with the technical requirements and, therefore acceptable. The sub-schedule (annexure 33) has been completed below to reflect these findings of the Technical Sub-committee. Note that this sub-schedule has been modified to show all three manufacturers on one form. In most cases, a separate sub-schedule form (Annexure 33) will be needed for each manufacturer as there will be more technical specification requirements to evaluate.

Annexure 33

Technical Evaluation Sub-Schedule for Table 5

INVITATION TO BID NUMBER: 07

Specification per Bidding Document	Alhambra Pharmaceuticals	Dalian Medicines	Garhiem Health Care
Norgestrel 030 mg and ethinyl estradiol 0.03 mg tablets	Acceptable	Acceptable	Acceptable
Ferrous Fumarate 75 mg tablets	Acceptable	Acceptable	Acceptable
Transparent blister pack with aluminum foil backing	Acceptable	Acceptable	Acceptable
5 year shelf life	Acceptable	Acceptable	Acceptable
Manufacturer has accepted Purchaser's pre-shipment inspection, sampling and testing rights	Acceptable	Acceptable	Acceptable

Remarks (acceptable or unacceptable. If unacceptable, provide reason.)

Overall Comments: The technical sub-committee members have reviewed and evaluated the technical information provided in each manufacturer proposal and have found that the contraceptive offered by each manufacturer meets the technical specification requirements identified in the invitation to bid package.

Signatures of technical sub-committee members and date:

_____ _____ _____

_____ _____ _____

Upon completing Annexure 33 the Technical evaluation committee completes a Summary of Technical Evaluation form (Annexure 34) that identifies whether the manufacturer or supplier was found overall to be compliant or non-compliant with the technical specification requirements. A completed Annexure 34 that shows all three bids as being compliant with the technical specifications is presented below. If one or more of the bids were not compliant with the technical specifications requirements, a reason for non-compliance would be provided on the form. A bid that is technically non-compliant is not considered for further evaluation.

Annexure 34. Summary of Technical Evaluation

(See next page)

Ministry of Population Welfare

Form SPF 4

Page 1 of 1

TABLE 2 – SUMMARY OF TECHNICAL EVALUATION

(ONLY BIDS THAT ARE RESPONSIVE)

Procurement Number					
Agency	Department/Project	Financial Year	Sequence Number	Bid Number	Contract Number

No.	Company	Technical Compliance	Comments (Reasons for non compliance)
1	**Alhambra Pharmaceuticals**	C/NC	**Compliant**
2	**Dalian Medicine**	C/NC	**Compliant**
3	**Garhiem Health Care**	C/NC	**Compliant**
4		C/NC	

KEY: **C DENOTES COMPLIANT** **NC DENOTES NON COMPLIANT**

This examination eliminated [number] companies, [Names of Companies]. List names of companies eliminated on separate sheet (s).

Attach Combined Technical Specification and Compliance Sheets for each Quotation/Tender if technical evaluation is complex.

Form SPF4

Bid verification

The purpose of bid verification is to review the bid to make sure the bid does not contain any significant deficiencies. As was done for the technical evaluation, for actual bid verification evaluation the bid evaluation committee should review the bid to identify items to be included in the bid verification checklist. In reviewing the bids, the evaluation committee should not take into consideration any additional information that the manufacturer provided that was not requested in the bidding document. The verification checklist (Annexure 35) has been completed below for this case study based on information from the bids contained in the Summary of Bid Information Table.

Annexure 35

Verification Checklist for SBEF Table 5 (Column b)

Verification Information	Alhambra Pharmaceuticals	Dalian Medicines	Garhiem Health Care
1. Bid form and price schedule filled in and duly signed?	Yes	Yes	Yes
2. Bid validity period conforms to the requirements in the bidding documents?	Yes	Yes	Yes
3. If the Bidder is a joint venture, Joint venture agreement provided?	Not applicable	Not applicable	Not applicable
4. If the bidder is not the manufacturer, whether bidder provided Manufacturer's confirmation to warranty obligations?	Not applicable	Not applicable	Not applicable
5. If the bid has been submitted by an agent, whether the manufacturer's Authorization to submit the bid is provided?	Not applicable	Yes	Yes

Eligibility verification

The bid evaluation committee reviews the bid documents and identifies requirements regarding the eligibility of the manufacturer to submit a bid. These requirements are then listed on the Eligibility checklist and the committee reviews each manufacturer's bid to confirm that they are eligible. A sample Eligibility checklist (Annexure 36) has been prepared for this case study using information found on the Summary of Bid Information Table. In an actual bid evaluation, other requirements specific to the bid would be included on the checklist. For example, in this case study pre-qualification of bidders was not conducted. If

pre-qualification of bidders had been conducted, only pre-qualified bidders would be eligible to submit bids. Also, for this case study we have assumed that the Government of Pakistan does not follow a list of eligible source countries.

Annexure 36

Eligibility Checklist for SBEF Table 5 (Column c)

Eligibility Information	Alhambra Pharmaceuticals	Dalian Medicines	Garhiem Health Care
1. Does the bidder appear on the list of black-listed firms posted on the Public Procurement Regulatory Authority website?	No	No	No
2. Does the bidder appear on the list of ineligible firms posted on the World Bank website? (Note: a link to the WB website is posted on the PPRA website)	No	No	No
3. Has the bidder been prequalified?	Not applicable	Not applicable	Not applicable
4. Is bidder a national of an eligible source country?	Not applicable	Not applicable	Not applicable
5. If bid is from a joint venture, is the joint venture registered in an eligible source country?	Not applicable	Not applicable	Not applicable
6. Do the goods offered originate from an eligible source country?	Not applicable	Not applicable	Not applicable
5. If the bidder is a publicly owned enterprise in Pakistan, is the bidder legally and financially autonomous and operating under commercial law?	Yes	Not applicable	Not applicable

Bid Security verification

The bid evaluation committee reviews the bid documents and identifies bid security requirements the manufacturer must comply with when submitting a bid. These requirements are then listed on the Bid Security checklist and the committee reviews each manufacturer's bid security to confirm that it meets the bidding document requirements. A sample Bid Security checklist (Annexure 37) has been prepared for this case study using information found on the Summary of Bid Information Table.

Annexure 37

Bid Security Checklist for SBEF Table 5 (Column d)

Eligibility Information	Alhambra Pharmaceuticals	Dalian Medicines	Garhiem Health Care
1. Is bid accompanied by a bid security?	Yes	Yes	Yes
2. Does the amount of the bid security conform to the amount required in the bidding document?	Yes	Yes	Yes
3. Does the period of the bid security conform to the period required in the bidding document?	Yes	Yes	Yes
4. If bid security is issued as a bank guarantee, is it consistent with the wording of the bid security form provided in the bidding document?	Not applicable	Not applicable	Not applicable
5. If the bid is submitted by a joint venture, is the bid security in the name of all of the partners of the joint venture?	Not applicable	Not applicable	Not applicable

Completeness of Bid verification

The bid evaluation committee reviews the bid documents to confirm that the bids are complete and to identify any deviations from the original bidding document requirements. Changes or additions to the bidding documents are usually considered deviations. Some deviations may be accepted by the bid evaluation committee if the deviations are simple, corrective, or explanatory in nature. Deciding whether a deviation is acceptable requires significant judgment of the Bid Evaluation Committee. A sample Completeness of Bid checklist (Annexure 38) has been prepared for this case study using information found on the Summary of Bid Information Table. Note that one of the bidders, Garhiem Health Care, included an addition to its bid. Since the addition was an explanation of why the second delivery would be two weeks after the requested date, the Bid Evaluation Committee decided that this deviation would be acceptable.

Annexure 38

Completeness of Bid Checklist for SBEF Table 5 (Column e)

Eligibility Information	Alhambra Pharmaceuticals	Dalian Medicines	Garhiem Health Care
1. Does the bidder offer all of the required items?	Yes	Yes	Yes
2. Does the bidder offer full quantities of the required items?	Yes	Yes	Yes
3. Has the bidder made any additions, deletions, or other changes to the original bidding documents?	No	No	Yes, included explanation of delivery delay for second shipment
4. Has the bidder initiated any erasures, additions, deletions or other changes to the original bidding documents?	No	No	No
5. Are all pages of the bidding document and the bid included in the submission?	Yes	Yes	Yes
6. Are all of the required documents and attachments included with the bid?	Yes	Yes	Yes

Commercial Responsiveness evaluation

The bid evaluation committee reviews the bid documents to confirm that the bids are commercially responsive to the original bidding document requirements. Major deviations to the commercial requirements and technical specifications are a basis for rejecting the bid. A sample Commercial Responsiveness sub-schedule (Annexure 39) has been prepared for this case study using information found on the Summary of Bid Information Table. Note that one of the bidders, Garhiem Health Care, has deviated from the required delivery date for the second shipment. Bids that offer deviations may be considered substantially responsive – at least as to the issue of fairness – if the deviation can be assigned a monetary value that would be added as a penalty during the financial evaluation process and if such deviation would be acceptable in the eventual contract. In this case, the Bid Evaluation Committee has decided to accept the deviation since a two week delay in the second delivery will not jeopardize the family planning programme. The Committee determined that a penalty of 1% of the value of the delayed shipment would be added to the total bid evaluation price for each week the shipment was delayed. This price deviation will be addressed later in Table 10 (annexure 43).

Annexure 39

Commercial Responsiveness Sub-Schedule for SBEF Table 5 (Column f)

Eligibility Information	Alhambra Pharmaceuticals	Dalian Medicines	Garhiem Health Care
1. Does the bidder ask for price adjustments when a fixed price bid was invited?	No	No	No
2. Does the bidder offer an alternative product in the bid?	No	No	No
3. What is the delivery time offered in the bid?	400,000 - 1/9/2010 400,000 - 1/12/2010	400,000 -1/9/2010 400,000 - 1/12/2010	400,000 - 1/9/2010 400,000 - 15/12/2010
4. Does the delivery time offered in the bid conform to the schedule of requirements in the Bidding Documents?	Yes	Yes	No
5. Is any sub-contracting mentioned in the bid?	No	No	No
6. Does the bidder agree to bear the responsibilities and liabilities allocated in the bidding documents, such as performance securities, insurance coverage, etc.? (If no, provide details)	Yes	Yes	Yes
7. Does the bidder agree to applicable law, taxes and duties, and dispute resolution procedures specified in the bidding documents? (if no, provide details)	Yes	Yes	Yes

Identify Substantially Responsive Bids

The findings of the Technical Evaluation and the Table 5 sub-schedule evaluations are reviewed for each bid and a determination is made as to whether a bid is considered to be substantially responsive to the bidding document requirements. The definition of "substantially responsive" is provided below.

"A bid is considered substantially responsive when it is presented in the required manner and appears to include all required information, samples, statements, securities, signatures, forms and supporting documents, and contains no material deviation from or reservations to the terms, conditions and specifications in the bidding documents."

As mentioned earlier, major deviations from the commercial requirements and technical specifications are a basis for the rejection of the bid. Significant judgment must be used in determining whether a bid is substantially responsive. If a bid is considered not substantially responsive and, therefore, not accepted for financial evaluation, a reason must be documented. Those bids that are deemed substantially responsive are then submitted for financial evaluation.

In this case study, the two week delay in the second delivery of oral contraceptives by Garhiem Health Care was not considered a significant deviation by the Bid Evaluation Committee and one that could be addressed through a price deviation penalty. Therefore, all three bids were submitted for financial evaluation.

Financial Evaluation

The purpose of the financial evaluation is to review each bid and arrive at a final "evaluated cost" for each bid. The "evaluated cost" is determined by taking corrections, discounts and other factors into consideration and assigning them a monetary value. The bid with the lowest "evaluated cost" is the bid that is selected for contract award. The bidding documents will contain the factors that must be considered in evaluating a bid price and determining an "evaluated cost".

Calculate Corrections and Unconditional Discounts

The first step in the financial evaluation of bids is to review the bid pricing and incorporate any corrections or unconditional discounts to help determine the "evaluated cost" of the bid. These adjustments are recorded on Table 6. Corrections and Unconditional Discounts (Annexure 40).

Corrections to a bid, for example, might be when there is a discrepancy between the amount in words and figures. In that case, the amount stated in words prevails and the amount in figures is corrected to match the amount in words. In the Case Study, there were no corrections required for pricing errors.

One bidder, Garhiem Health Care, offered an unconditional discount of 5% off of the total offered price. A sample Table 6 has been completed below to illustrate how to incorporate this price adjustment.

Annexure 40

Table 6. Corrections and Unconditional Discounts

Bidder	Read-out Bid Price(s)		Corrections		Corrected Bid Price(s)	Unconditional Discounts[2]		Corrected/ Discounted Bid Price(s)
	Currency	Amount	Computational Errors[1]	Provisional Sums		Percent	Amount(s)	
(a)	(b)	(c)	(d)	(e)	(f) = (c) + (d) - (e)	(g)	(h)	(i) = (f) – (h)
Alhambra Pharmac.	Rupee	42,400,000	0	0	42,400,000	0	0	42,400,000 R
Dalian Medicines	Yuan	3,440,000	0	0	3,440,000	0	0	3,440,000 Y
Garhiem Health Care	Mark	880,000	0	0	880,000	5		836,000 M
etc.								

Note: Only bids accepted for preliminary examination (Table 5, column *g*) should be included in this and subsequent tables. Columns *a*, *b*, and *c* are from Table 4 (columns *a*, *d*, and *e*, respectively).

[1] Corrections in column *d* may be positive or negative.

[2] If the discount is offered as a percent, column *h* is normally the product of the amounts in columns *f* and *g*. Refer to para. 6(c). If the discount is provided as an amount, it is entered directly in column *h*. A price increase is a negative discount.

Document exchange rates

The next step is to identify the currency that will be used for the purpose of comparing the "evaluated cost" of the bids. In the Case Study, the currency of comparison is the Pakistani Rupee. Select a published exchange rate that is close to the date of the bid opening. In our Case Study, the Bid Evaluation Committee obtained a copy of the exchange rates published by the State Bank of Pakistan on April 10, 2010, the date of the Bid Opening. Complete Table 7, Exchange Rates (Annexure 41) and attach a copy of the published exchange rates to the form. A sample Table 7, Exchange Rates, has been completed below for the Case Study.

Annexure 41

Table 7. Exchange Rates

Bidder: Alhambra Pharmaceuticals, Dalian Medicines, Garhiem Health Care

Currency Used for Bid Evaluation: Pakistani Rupee

Effective Date of Exchange Rate: April 10, 2010

Authority or Publication Specified for Exchange Rate: State Bank of Pakistan

Note: Attach copy of exchange rates provided by specified authority or publication.

State Bank of Pakistan
Exchange Rate of April 10, 2010

Currency (one unit)	Exchange rate for Rupee
Yuan	12.36
Mark	53.23

Calculate Currency Conversion

Using the published exchange rates from Table 7 (Annexure 41), the Bid Evaluation Committee converts the bid prices from foreign currencies into Pakistani Rupees using Table 8, Currency Conversion (Annexure 42). A sample Table 8 has been completed below for the Case Study to show conversion of Chinese Yuan and German marks into Pakistani Rupees.

Annexure 42

Table 8. Currency Conversion (Multiple Currencies)

Specify Evaluation Currency: Pakistani Rupees

Bidder	Currency(ies) of Bid	Corrected/Discounted Bid Price(s)	Applicable Exchange Rate(s)[1]	Evaluation Currency	
				Bid Price(s)	Total Bid Price[2]
(a)	(b)	(c)	(d)	(e) = (c) x (d)	(f)
Alhambra Pharmaceuticals	Rupee	42,400,000	1	42,400,000	42,400,000
Dalian Medicines	Yuan	3,440,000	12.36	42,518,400	42,518,400
Garhiem Health Care	Mark	836,000	53.23	44,500,280	44,500,280
etc.					

Note: This table is to be used for SBDG and Option B of SBDLW. Columns *a*, *b* and *c* are from Table 6, columns *a*, *b* and *i*.

[1] Column *d* is from Table 7.

[2] Column *f* is the sum of bid prices in column *e* for each bidder.

Calculate Additions, Adjustments and Priced Deviations

As noted earlier, one Bidder, Garhiem Health Care, did not fully comply with the requested delivery schedule and offered a second delivery that would be delayed by two weeks from the bidding document requested delivery date of 12/1/2010. The Bid Evaluation Committee agreed to accept this deviation, but would apply cost penalty of 1% of the value of the delayed shipment which would be added to the total bid evaluation price for each week the shipment was delayed. This price adjustment is addressed in Table 10 Additions, Adjustments and Price Deviations (Annexure 43) below.

The value of the delayed second Garhiem Health Care shipment is one half of the current "evaluated total" cost which is equal to Rs 22,250,140. With a price deviation penalty of 1% per week of this value for two weeks, the total price deviation penalty is 22,250,140 x .02 = Rs 445,002. This amount is inserted in column d of Table 10 and added to the bid price for Garhiem Health Care to reflect a new Total Bid Price.

Annexure 43

Table 10. Additions, Adjustments and Priced Deviations

Specify Evaluation Currency: Pakistani Rupees

Bidder	Corrected/ Discounted Bid Price[1]	Additions[2]	Adjustments[2]	Priced Deviations[2]	Total Price
(a)	(b)	(c)	(d)	(e)	(f) = (b) + (c) + (d) + (e)
Alhambra Pharmaceuticals	42,400,000	0	0	0	42,400,000
Dalian Medicines	42,518,400	0	0	0	42,518,400
Garhiem Health Care	44,500,280	0	445,002	0	44,945,282
etc.					

[1] Column *b* is from either Table 8, column *f* or Table 9, column *j*.

[2] Each insertion in columns *c*, *d*, or *e* should be footnoted and explained in adequate detail, accompanied by calculations. Refer to paras. 6(e), 6(f), and 6(g) respectively of Annex I

Calculate Domestic Preference for Goods

Domestic preference is subject to the approval of the Ministry of Commerce and would require a Specific Notification (SRO) to be used in a bid evaluation. In most cases, domestic preference is applied to engineering services procurement and is not applied for goods (contraceptives) procurement. When domestic preference is not applied, the next step in the case study would be to complete the Bid Ranking worksheet using the Total Bid prices from Table 10. However, to demonstrate how a domestic preference would be applied in a bid evaluation, we have completed a sample Table 11 form. For this sample demonstration, we are assigning a preference of 15% for goods manufactured in Pakistan.

Table 11, Domestic Preference for Goods (Annexure 44), is a World Bank form that has been adapted to allow adjustment to bid prices to be made to address domestic preference requirements. The World Bank divides manufacturers into three categories when considering domestic preference. For this Case Study, column b is used to indicate whether a manufacturer qualifies for the domestic preference. Only Alhambra Pharmaceuticals, a local manufacturer in Pakistan, qualifies for the domestic preference consideration. A sample Table 11 (Annexure 44) has been completed to show how domestic preference is applied to determine a total "evaluated cost" for each bid.

Total evaluated bid prices from Table 10 are added to column c of Table 11. Price deviations are not considered when calculating domestic preference so the price deviation Garhiem Health Care had added to its price due to the late second delivery date is subtracted from the column c figure to provide a revised total price for column e of Table 11. In this Case Study, prevailing tariffs are not applicable. 15% of the revised total cost in column c for Dalian Medicines and Garhiem Health Care is placed in column h. This preference price is added to the revised total price to obtain a Total Comparison Price.

As seen by completing Table 11, in this example it did not make a difference in the ranking of bids since Alhambra Pharmaceuticals already offered the lowest priced bid. If, however, the bid from Alhambra was higher than the other two bids, applying a domestic preference to the other two bids might raise their bid price high enough to make Alhambra Pharmaceuticals the lowest bidder.

Annexure 44. Table 11. Domestic Preference for Goods

Specify Evaluation Currency: Pakistani Rupees

Bidder *(a)*	Domestic Preference Group[1] *(b)*	Total Price[2] *(c)*	Exclusions for Preference[3] *(d)*	Revised Total *(e) = (c) – (d)*	Prevailing Tariff (%)[4] *(f)*	Domestic Preference (%)[5] *(g)*	Preference Price[6] *(h)*	Total Comparison Price *(i) = (c) + (h)*
Alhambra Pharmaceutl.	Yes	42,400,000	0	42,400,000	n/a	0	0	42,400,000
Dalian Medicines	No	42,518,400	0	42,518,400	n/a	15	6,377,760	48,896,160
Garhiem Health Care etc.	No	44,945,282	445,002	44,500,280	n/a	15	6,675,042	51,175,322

[11] Column *b* refers to Groups A, B, or C, as indicated by bidder, subject to verification by Borrower.

[2] Column *c* is from Table 10, column *f*. If the lowest total price is from a Group A or Group B bidder, it is the lowest evaluated bidder, and the remainder of the table need not be filled out. Columns *d* through *h* need to be filled out only for Group C bids.

[3] Column *d* is the sum of costs in columns *d* and *e* from Table 10 plus other costs incurred within the Borrower's country. Footnotes should be provided to explain the significant components of column *d*.

[4] Column *f* is the sum of duties and import taxes on the particular items or group of similar items as a percent of the CIF or CIP price. Refer to para. 7(a) of Annex I.

[5] Column *g* will be the smaller of 15 percent or the prevailing tariff in column *f*.

[6] Column *h* for Group A bidders is zero. Group B bids at this stage should no longer be compared. For Group C bidders, column *h* is the product of columns *e* and *g*.

Complete Bid Ranking Worksheet

The final step in this Case Study is to complete the Bid Ranking Worksheet (Annexure 45) which lists the bids in order of their ranking for recommendation for contract award. Since we are not applying a domestic preference to this bid evaluation, the total Comparison Price from Table 10 is used for the Total Bid Price for the Ranking Worksheet instead of Table 11 prices. There were no cross discounts offered in this case study, so no further adjustments are made to the Total bid Price. The manufacturer whose bid is ranked number 1 is recommended for contract award. If a contract is not issued to the first ranked manufacturer, the second ranked manufacturer is then selected for contract award. A sample Ranking Worksheet (Annexure 45) for the Case Study is completed below.

Annexure 45

Ranking Worksheet

Bid no. 07

Bid Opening Date: April 10, 2010

Bidder	Total Bid Price	Ranking*
Alhambra Pharmaceuticals	42,400,000	1
Dalian Medicines	42,518,400	2
Garhiem Health Care	44,945,282	3

- Prior to any cross discounts that may be applicable

Summary of Bid Information Table

Oral Contraceptive Invitation to Bid Request

Information/ Requirements	Alhambra Pharmaceuticals	Dalian Medicines	Garhiem Health Care
Country of Manufacture	Pakistan	China	Germany
Currency of Bid	Pakistani Rupees	Chinese Yuan	German Deutsche Mark
Quoted Unit Price	53 Rupees	4.3 Yuan	1.1 Mark
Quantity requested 800,000 cycle	800,000 cycles	800,000 cycles	800,000 cycles
Total Bid Price	42,400,000 Rupees	3,440,000 Yuan	880,000 Marks

Information/ Requirements	Alhambra Pharmaceuticals	Dalian Medicines	Garhiem Health Care
Bid Price Basis	FOB Factory Karachi	CIF Karachi	CIF Karachi
Delivery requested 400,000 - 9/1/2010 400,000 -12/1/2010	400,000 - 1/9/2010 400,000 - 1/12/2010	400,000 - 1/9/20100 400,000 - 1/12/2010	400,000 - 1/9/20100 400,000 - 15/12/2010
Discount offered	No	No	Yes – 5%
Technical Requirements			
Norgestrel (0.30 mg) & ethinyl estradiol (0.03 mg) tablets (21)	Norgestrel (0.30 mg) & ethinyl estradiol (0.03 mg) tablets (21)	Norgestrel (0.30 mg) & ethinyl estradiol (0.03 mg) tablets (21)	Norgestrel (0.30 mg) & ethinyl estradiol (0.03 mg) tablets (21)
Ferrous fumarate (75 mg) tablets (7)	Ferrous fumarate (75 mg) tablets (7)	Ferrous fumarate (75 mg) tablets (7)	Ferrous fumarate (75 mg) tablets (7)
Transparent blister pack with aluminum foil backing	Transparent blister pack with aluminum foil backing	Transparent blister pack with aluminum foil backing	Transparent blister pack with aluminum foil backing
Shelf Life 5 years	Shelf Life 5 years	Shelf Life 5 years	Shelf Life 5 years
Proper identification markings on individual blister pack	Proper identification markings on individual blister pack	Proper identification markings on individual blister pack	Proper identification markings on individual blister pack
Regulatory Requirements			
Registered in Pakistan	Yes	Yes	Yes
Registered Manufacturer agent in Pakistan	Not applicable	Yes	Yes
Verification Requirements			
Bid forma and price schedule complete and signed	Yes	Yes	Yes
Bid valid for required period	Yes	Yes	Yes

Information/ Requirements	Alhambra Pharmaceuticals	Dalian Medicines	Garhiem Health Care
Is bid submitted by a joint venture?	No	No	No
If joint venture, is joint venture agreement provided?	Not applicable	Not applicable	Not applicable
If bidder is not the manufacturer, has bidder provided Manufacturer's warranty confirmation?	Not applicable	Not applicable	Not applicable
Is bid submitted by a registered agent of the manufacturer?	No	Yes	Yes
Has manufacturer provided authorization for agent to submit bid?	Not applicable	Yes	Yes
Bid Security Requirements			
Bid accompanied by Bid Security	Yes	Yes	Yes
Does Bid Security amount meet bidding document requirement?	Yes	Yes	Yes
Does period of bid security meet bid requirements?	Yes	Yes	Yes
If a bank guarantee issued, is wording consistent with bid security form provided in bidding document?	Not applicable	Not applicable	Not applicable
If bid submitted by joint venture, is bid security in name of all joint venture partners?	Not applicable	Not applicable	Not applicable
Completeness of Bid Requirements?			

Information/ Requirements	Alhambra Pharmaceuticals	Dalian Medicines	Garhiem Health Care
Does the bidder offer all of the required items?	Yes	Yes	Yes
Does the bidder offer full quantities of the required items?	Yes	Yes	Yes
Has the bidder made any additions, deletions, or other changes to the original bidding documents?	No	No	Yes, included explanation of delivery delay for second shipment
Has the bidder initiated any erasures, additions, deletions or other changes to the original bidding documents?	No	No	No
Are all pages of the bidding document and the bid included in the submission?	Yes	Yes	Yes
Are all of the required documents and attachments included with the bid?	Yes	Yes	Yes
Commercial Responsiveness Requirements			
Does the bidder ask for price adjustments when a fixed price bid was invited?	No	No	No
Does the bidder offer an alternative product in the bid?	No	No	No
What is the delivery time offered in the bid?	400,000 - 1/9/2010 400,000 - 1/12/2010	400,000 -1/9/2010 400,000 - 1/12/2010	400,000 - 1/9/2010 400,000 - 15/12/2010

Information/ Requirements	Alhambra Pharmaceuticals	Dalian Medicines	Garhiem Health Care
Does the delivery time offered in the bid conform to the schedule of requirements in the Bidding Documents?	Yes	Yes	No
Is any sub-contracting mentioned in the bid?	No	No	No
Does the bidder agree to bear the responsibilities and liabilities allocated in the bidding documents, such as performance securities, insurance coverage, etc.? (If no, provide details)	Yes	Yes	Yes
Does the bidder agree to applicable law, taxes and duties, and dispute resolution procedures specified in the bidding documents? (if no, provide details)	Yes	Yes	Yes

Annexure 54. Sample Format for Notification of Acceptance

Sample Format For Notification of Acceptance

Memo No._____ Date

Government of Pakistan
Ministry of Population Welfare
(Mention address)

To
M/S *(mention name and address of the bidder)*

Subject: Award Notification against bid package no.____ for supplying
(mention short description of goods)

Dear Sirs,

We are pleased to award you the contract for bid package no. *(mention no.)* for the goods and price as mentioned below:

Bid Package No. and short Description of goods	Total Contract Price with Currency	Basis of Contract
(mention short description of goods)	*(mention price with currency)*	*(mention whether it is a CIF or CFR or EXW contract or otherwise)*

Please note that the contract will include, among others, the following documents:

i) The Form of Contract;
ii) The Bid Form and the Price Schedule submitted by the Bidder;
iii) The Schedule of Requirements (offered by the Bidder and accepted by the Purchaser);
iv) The Technical Specifications (offered by the Bidder and accepted by the Purchaser);
v) The General Conditions of Contract;
vi) The Special Conditions of Contract (duly filled in); and,
vii) The Performance Security submitted by the Bidder.

Two copies of the contract form are enclosed herewith for your signing and returning to us. Please also submit a Performance Security in the amount not less than *(mention percentage) of the contract price* within *(mention number of days)* of receipt of this award notification.

Annexure 55. Sample Instructions for Letter of Credit Application

Instructions for Letter of Credit Application

Date: _____

Attention: (Finance unit or department that handles L/C requests)

Reference: (Contract or Purchase Order number)

Please instruct our bank to open an irrevocable, confirmed, documentary Letter of Credit as follows:

1. Beneficiary: _____ (Seller's name and address)
   _____
   _____
   _____
2. Advising Bank: _____ (Bank's name and address)
   _____
   _____
3. L/C Amount _____
4. Shipping Terms: _____
5. Shipment Via: _____
6. Shipping Date: _____
7. L/C Expiration Date: _____
8. Shipment From: _____
9. Shipment To: _____
   (Port or airport, city, and country of final destination)
10. Merchandise Description: _____
11. Merchandise Value: _____
    (Include any down payments not contained in the L/C amount.)
12. Partial Shipments: _____ not allowed _____ allowed
13. Trans-shipments: _____ not allowed _____ allowed
14. Documents Required:

This requirement varies from country to country. Please review your country's import requirements as well as your own agency's requirements. Typical shipping document for *airfreight* shipments are included below:

- Commercial Invoice (state number of each required)

  _____ originals _____ copies

- Packing List (state number of each required)

  _____ originals _____ copies

- Original Air Waybill (state number of each required) consigned to:

  _____

  _____ originals _____ copies

- Insurance Certificate for 110% of CIP value (state number of each required)

  (Insure for total cost of commodities, transportation and insurance plus minimum 10 percent. Total cost of commodities includes down payment to supplier not included in L/C amount.)

  _____ originals _____ copies

  Insurance payable to: _____

- Certificate of Conformity with contract specifications issued by _____ _____(third party inspection agent).

- Beneficiary's signed certification that the following documents have been sent with the shipment (list required documentation).

  _____

  _____

- Beneficiary's signed certification that all the shipping boxes have been labelled with the following Shipping Marks:

15. Special L/C Conditions:
16. L/C Transmittal Method: _____ Airmail _____ Full Text Cable ____Electronic

Annexure 56. Responsibilities for Contract Performance

Responsibilities for Contract Performance (Example)

Supplier

1. Provides performance security.
2. Notifies purchaser in writing of all subcontracts awarded under contract, if not stated in bid.
3. Provides reasonable facilities and assistance to inspection agents, including access to production data and quality control records, for inspection purposes.
4. Provides packing sufficient to prevent damage or deterioration of goods during transit.
5. Includes appropriate temperature monitoring devices with packing, if needed.
6. Complies with requested routing.
7. Arranges and pays for shipping and insurance (CIF terms).
8. Notifies purchaser by fax, telex, cable, or e-mail of full details of shipment.
9. Forwards shipping documents and quality assurance documents to purchaser.
10. Delivers goods in accordance with time schedule of the contract.
11. Requests payment in writing from purchaser (or purchaser's bank).
12. Pays taxes, stamp duties, license fees, and any other levies imposed outside of the destination country (foreign supplier).
13. Pays taxes, duties, and license fees incurred or imposed locally, prior to delivery (local supplier).
14. Replaces rejected goods.
15. Notifies purchaser in writing of any impending delay in delivery, its likely duration, and its causes.
16. Claims any adjustment in price within 30 days after receipt of change order.
17. Notifies purchaser in writing of any *force majeure* situation.

Purchaser

1. Opens Letter of Credit in favour of supplier.
2. Arranges and prepares for pre- and post-shipment inspections and tests.
3. Pays for pre-shipment inspections and tests.
4. Notifies supplier (in writing) of identity of any representatives retained for inspections and tests.
5. Authorizes (in writing) shipment of goods based on pre-shipment inspection and test results.
6. Provides transportation of goods after delivery.

7. Arranges for payment of contract price to supplier upon receipt of invoice and documents.
8. Provides Acceptance Certificate for each delivery.
9. Discharges and returns performance security to supplier not later than 30 days following the date of completion of the supplier's performance obligation, including any warranty obligation, under the contract.
10. Notifies supplier (in writing) of any claims arising under warranty.
11. Issues change orders (in writing) to supplier for any modification to specifications, method of shipment, place of delivery, or services.
12. Notifies supplier (in writing) of default(s).
13. Notifies supplier (in writing) of intention to terminate contract for any reason

Annexure 57. Estimated Schedule for Contract Performance and Shipping

Sample Contract Performance Timeline

Task Name	Resource Name	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6
Sign Contract	Supplier						
Arrange Performance Security	Supplier						
Open Letter of Credit	Purchaser						
Production Period	Supplier						
Arrange Inspection and Testing	Purchaser						
Pre-shipment Inspection and Test							
Authorize Shipment	Purchaser						
Arrange Shipment and Insurance	Supplier						
Notify Shipping Details	Supplier						
Forward Shipping Documents	Supplier						
Shipping Period							
Delivery Date							
Customs Clearance	Purchaser						
Receiving Inspection	Purchaser						
Release							

Annexure 58. Sample Shipping and Marking Instructions

Shipping Instructions

To: _____*(insert Supplier's name)*

Contract No. _____

For Shipment(s) to Consignee/Purchaser

(Ministry of Population Welfare, Government of Pakistan)

Prior to Shipment of Commodities

1. Contact _____*(insert name and address of contracted inspection agent/company)*

Upon Receipt of Authorization for Shipment

2. Assemble packed, marked, inspected and approved unit packages on a pallet base selected to best utilize the space of a standard 20 foot shipping container. Secure load tightly and firmly, without an overhang, using horizontal and vertical strapping. Plastic shrink wrap may be used to stabilize and protect palletized loads.

3. Arrange for a sufficient number of standard 20 foot containers to accommodate shipment. Goods may not be consolidated with other freight.

4. Prior to loading, shipping containers must be inspected for cleanliness, safety (free from splinters, snags, dents, or bulges), security (door gaskets, seals, hardware, fittings, etc.), watertight integrity and overall container seaworthy condition. Contents shall be verified and containers sealed in the presence of an insurance surveyor. A written surveyor's report attesting to the above conditions is required.

5. Load containers to the optimum degree possible without damage to the shipping cartons. Fill all voids by bracing or using fillers to prevent sliding or shifting of cargo. Provide plastic or water-repellent shrouds over the top and sides of the load to protect against damage from condensation that may accumulate on interior container surfaces.

6. Ship in standard 20 foot containers via ocean freight on flag vessel of _____(*insert country*), to : _____(*insert name and address of consignee including city and country*)

7. Commodities must be insured for 110% of their total CIF value covering all risks from warehouse to port of unloading.

8. Do not ship freight "collect". Freight must always be "prepaid".

9. Documentation requirements are as follows:
   - Commercial Invoice
   - Packing List
   - Bill of Lading
   - Certificate of Origin
   - Insurance Certificate
   - Certificate of Analysis
   - Societie General Surveillance (SGS) Clean Report of Findings
   - Insurance Surveyor's Report

10. Commercial Invoice must state:
    - Name and address of supplier/shipper
    - Name and address of consignee
    - Invoice number
    - Date of invoice
    - Letter of Credit number
    - Contract number
    - Place and date of shipment
    - Number of shipping cartons
    - Weight of each shipping carton
    - Number of pallets' number of shipping cartons per pallet

- Number of containers; number of pallets per container
- Lot number(s) and quantities shipped
- Complete description of product, including expiry date
- Unit price of product
- Total FOB value of shipment
- Freight and insurance charges
- Total CIF value of shipment
- Gross weight of shipment
- Country of origin

Marks:_____(*insert*)

Port of Destination: _____(*insert*)

Notify Consignee Upon Arrival at _____(*insert telephone number*)

11. Bill of Lading (B/L) must include container number(s), contract number, letter of credit number, and country of origin in addition to standard B/L information requirements.

12. Send to _____(*insert consignee's name)* via special courier, two sets of the following shipping documents (copies are acceptable where originals are required by bank for payment under Letter of Credit):
    - Signed commercial invoice
    - Packing list
    - Bill of Lading
    - Certificate of Origin
    - Insurance Certificate
    - Certificate of Analysis
    - Societie General Surveillance (SGS) Clean Report of Findings
    - Insurance Surveyor's Report

13. At least seven days in advance of shipment, advise_____(*insert consignee's name*) via fax or e-mail:
    - Contract number
    - Vessel's name and voyage number
    - Booking number
    - Container number(s)
    - Estimated departure date and estimated date and time of arrival (ETA) at _____(*insert port of destination*).
    - Bill of Lading number
    - Quantity of product shipped
    - Number of shipping cartons
    - Number of containers
    - Weight and total value of shipment.

Annexure 59. Sample Inspection Order

Sample Inspection Order

To: _____(*insert name of inspection agent/company*)

Date:

Contract Number:

Vendor: XYZ Corporation

Consignee: MOPW, Government of Pakistan

INSPECTION ORDER

Inspect packing and marking for compliance with section _____ of attached technical specifications.

Inspection shall be conducted in accordance with ISO 2859-1, Inspection by Attributes

Inspection level shall be S-3 with an AQL of 2.5%:

For exterior shipping cartons, the lot size shall be the number of exterior shipping cartons and the sample unit shall be one exterior shipping carton.

For other levels of packing, the lot size shall be the number of inner boxes and the sample unit shall be one inner box.

1. Inspect and score for defects as follows:

Defects*	
Contents	Quantity of goods not as specified; packets or strips not as specified
Marking	Omitted; incorrect; illegible; of an improper size, location, sequence, or method of application
Materials	Packaging/packing materials not as specified, missing, damaged, or not serviceable
Workmanship	Shipping cartons inadequately closed and secured; poor application of internal packaging and packing material; distorted inner boxes

* Examination of defects of closure shall be performed on units fully prepared for delivery.

a. Exterior shipping cartons selected at random from lot proposed for delivery.

b. Inner boxes selected at random from sample shipping cartons.

2. Examine Documentation

Refer to attached Shipping Instructions and confirm all documents listed are complete.

Confirm that values appearing on Certificates of Analysis for the lot(s) prepared for shipment are within the range mentioned in the product's National Regulatory Authority (NRA) dossier and/or specified in the relevant pharmacopoeia per the procurement specification.

3. Provide a written report for approval by the Government of Pakistan on packing and marking and documentation prior to release of a clean bill of goods.

4. Unless otherwise specified in writing, the inspection agent is not authorized to sign the "Authorization for Shipment" form.

Annexure 60. Sample Authorization for Shipment

Authorization for Shipment

Attn: _____ [supplier's name]

Ref: Contract Number _____

Letter of Credit Number _____

Authorization for Shipment

Re: _____ [description of goods]

Pre-shipment inspection and test data have been received and approved by:

_____ [Purchaser]

Signature

Signature of this document by the authorized representative indicates that the commodity conforms to the Contract Number_____ and is released for shipment.

This certificate does not release supplier from compliance with warranties and other conditions included in this contract.

_____

Authorized Representative

_____

Date

Appendix I: Public Procurement Rules 2004

Islamabad, June 9, 2004

NOTIFICATION

S.R.O 432(I)/2004. In exercise of the powers conferred by section 26 of the Public Procurement Regulatory Authority Ordinance, 2002 (XXII of 2002), the Federal Government is pleased to make the following rules, namely:

1. Short title and commencement

(1) These rules may be called the Public Procurement Rules, 2004.

(2) They shall come into force at once.

GENERAL PROVISIONS

2. Definitions

(1) In these rules, unless there is anything repugnant in the subject or context,

(a) "bid" means a tender, or an offer, in response to an invitation, by a person, consultant, firm, company or an organization expressing his or its willingness to undertake a specified task at a price;

(b) "bidder" means a person who submits a bid;

(c) "competitive bidding" means a procedure leading to the award of a contract whereby all the interested persons, firms, companies or organizations may bid for the contract and includes both national competitive bidding and international competitive bidding;

(d) "contractor' means a person, consultant, firm, company or an organization who undertakes to supply goods, services or works;

(e) "contract" means an agreement enforceable by law;

(f) "corrupt and fraudulent practices" includes the offering, giving, receiving, or soliciting of anything of value to influence the action of a public official or the supplier or contractor in the procurement process or in contract execution to the detriment of the procuring agencies; or misrepresentation of facts in order to influence a procurement process or the execution of a contract, collusive practices among bidders (prior or after bid submission) designed to establish bid prices at artificial, non-competitive levels and to

deprive the procuring agencies to the benefits of free and open competition and any request for, or soliciting of anything of value by any public official in the course of the exercise of his duty;

(g) "emergency" means natural calamities, disasters, accidents, war and operational emergency which may give rise to abnormal situation requiring prompt and immediate action to limit or avoid damage to person, property or the environment;

(h) "lowest evaluated bid" means:

(i) a bid most closely conforming to evaluation criteria and other conditions specified in the bidding document; and

(ii) having lowest evaluated cost;

(i) "Ordinance" means the Public Procurement Regulatory Authority Ordinance, 2002 (XXII of 2002);

(j) "repeat orders" means procurement of the same commodity from the same source without competition and includes enhancement of contracts;

(k) "supplier" means a person, consultant, firm, company or an organisation who undertakes to supply goods, services or works; and

(l) "value for money" means best returns for each rupee spent in terms of quality, timeliness, reliability, after sales service, up-grade ability, price, source, and the combination of whole-life cost and quality to meet the procuring agency's requirements.

(2) The expressions used but not defined in these rules shall have the same meanings as are assigned to them in the Ordinance.

3. Scope and applicability

Save as otherwise provided, these rules shall apply to all procurements made by all procuring agencies of the Federal Government whether within or outside Pakistan.

4. Principles of procurement

Procuring agencies, while engaging in procurements, shall ensure that the procurements are conducted in a fair and transparent manner, the object of procurement brings value for money to the agency and the procurement process is efficient and economical.

5. International and inter-governmental commitments of the Federal Government

Whenever these rules are in conflict with an obligation or commitment of the Federal Government arising out of an international treaty or an agreement with a State or States, or any international financial institution the provisions of such international treaty or agreement shall prevail to the extent of such conflict.

6. Language

(1) All communications and documentation related to procurements of the Federal Government shall either be in Urdu or English or both. Except where a procuring agency is situated outside the territories of Pakistan and procurements are to be made locally, the procuring agency may use the local language in addition to Urdu or English.

(2) Where the use of local language is found essential, the original documentation shall be in Urdu or English, which shall be retained on record; for all other purposes their translations in local language shall be used:

Provided that such use of local language ensures maximum economy and efficiency in the procurement.

(3) In case of the dispute reference shall be made to the original documentation retained on record.

7. Integrity pact

Procurements exceeding the prescribed limit shall be subject to an integrity pact, as specified by regulation with approval of the Federal Government, between the procuring agency and the suppliers or contractors.

PROCUREMENT PLANNING

8. Procurement planning

Within one year of commencement of these rules, all procuring agencies shall devise a mechanism for planning in detail for all proposed procurements with the object of realistically determining the requirements of the procuring agency, within its available resources, delivery time or completion date and benefits that are likely to accrue to the procuring agency in the future.

9. Limitation on splitting or regrouping of proposed procurement

Save as otherwise provided and subject to the regulation made by the Authority, with the prior approval of the Federal Government, a procuring agency shall announce in an appropriate manner all proposed procurements for each financial year and shall proceed accordingly without any splitting or regrouping of the procurements so planned. The annual requirements thus determined would be advertised in advance on the Authority's website as well as on the website of the procuring agency in case the procuring agency has its own website.

10. Specifications

Specifications shall allow the widest possible competition and shall not favour any single contractor or supplier nor put others at a disadvantage. Specifications shall be generic and shall not include references to brand names, model numbers, catalogue numbers or similar classifications. However, if the procuring agency is convinced that the use of or a reference to a brand name or a catalogue number is essential to complete an otherwise incomplete specification, such use or reference shall be qualified with the words "or equivalent".

*Provided that this rule shall not apply to procurement made by public sector commercial concerns on the demand of private sector client specifying, in writing, a particular brand, model or classification of equipment, machinery or other objects.

**Amended vide Cabinet Division No.5/37/2005-M-III/Admin (PPRA), dated 23-09-2008*

11. Approval mechanism

All procuring agencies shall provide clear authorization and delegation of powers for different categories of procurement and shall only initiate procurements once approval of the competent authorities concerned has been accorded.

PROCUREMENT ADVERTISEMENTS

12. Methods of advertisement

*(1) Procurements over one hundred thousand rupees and up to the limit of two million rupees shall be advertised on the Authority's website in the manner and format specified by regulation by the Authority from time to time. These procurement opportunities may also be advertised in print media, if deemed necessary by the procuring agency:

*Provided that the lower financial limit for advertisement on Authority's website for open competitive bidding shall be the prescribed financial limit for request for quotations under clause (b) of rule 42.

*(2) All procurement opportunities over two million should be advertised on the Authority's website as well as in other print media or newspapers having wide circulation. The advertisement in the newspapers shall principally appear in at least two national dailies, one in English and the other in Urdu.

(3) In the case where the procuring agency has its own website it may also post all advertisements concerning procurement on that website as well.

(4) A procuring agency utilizing electronic media shall ensure that the information posted on the website is complete for the purposes for which it has been posted, and such information shall remain available on that website until the closing date for the submission of bids.

**Amended vide Cabinet Division No. 5/37/2005-M-III/Admin (PPRA), Dated 13-12-2006*

13. Response time

*(1) The procuring agency may decide the response time for the receipt of bids or proposals (including proposals for pre-qualification) from the date of publication of an advertisement or notice, keeping in view the individual procurement's complexity, availability and urgency. However, under no circumstances the response time shall be less than fifteen days for national competitive bidding and thirty days for international competitive bidding from the date of publication of advertisement or notice.

All advertisements or notices shall expressly mention the response time allowed for that particular procurement along with the information for collection of bid documents which shall be issued till a given date, allowing sufficient time to complete and submit the bid by the closing date:

Provided that no time limit shall be applicable in case of emergency.

(2) The response time shall be calculated from the date of first publication of the advertisement in the newspaper or posting on the website, as the case may be.

(3) In situations where publication of such advertisements or notices has occurred in both electronic and print media, the response time shall be calculated from the day of its first publication in the newspapers.

14. Exceptions

*It shall be mandatory for all procuring agencies to advertise all procurement requirements exceeding prescribed financial limit which is applicable under sub-clause (i) of clause (b) of rule 42. However, under following circumstances deviation from the requirement is permissible with the prior approval of the Authority:

(a) the proposed procurement advertisement is related to national security and its publication could jeopardize national security objectives; and

(b) the proposed procurement advertisement or notice or publication of it, in any manner, relates to disclosure of information, which is propriety in nature or falls within the definition of intellectual property which is available from a single source.

**Amended vide Cabinet Division No. 5/37/2005-M-III/Admin (PPRA), Dated 13-12-2006*

PRE-QUALIFICATION, QUALIFICATION AND DIS-QUALIFICATION OF SUPPLIERS AND CONTRACTORS

15. Pre-qualification of suppliers and contractors

(1) A procuring agency, prior to the floating of tenders, invitations to proposals or offers in procurement proceedings, may emerge in pre-qualification of bidders in case of services, civil works, turnkey projects and in case of procurement of expensive and technically complex equipment to ensure that only technically and financially capable firms are invites to submit bids. Such pre-qualification shall solely be based on upon the ability of the interested parties to perform that particular work satisfactorily.

(2) A procuring agency while engaging in pre-qualification may take into consideration the following factors, namely:

(a) relevant experience and past performance;

(b) capabilities with respect to personnel, equipment, and plant;

(c) financial position;

(d) appropriate managerial capability; and

(e) any other factor that a procuring agency may deem relevant, not inconsistent with these rules.

16. Pre-qualification process

(1) The procuring agency engaging in pre-qualification shall announce, in the pre-qualification documents, all information required for pre-qualification, including instructions for preparation and submission of the pre-qualification documents, evaluation criteria, list of documentary evidence required by suppliers or contractors to demonstrate their respective qualifications and any other information that the procuring agency deems necessary for pre-qualification.

(2) The procuring agency shall provide a set of pre-qualification documents to any supplier or contractor, on request and subject to payment of price, if any.

Explanation: For the purposes of this sub-rule price means the cost of printing and providing documents only.

(3) The procuring agency shall promptly notify each supplier or contractor submitting an application to pre-qualify whether or not it has been pre-qualified and shall make available to any person directly involved in the pre-qualification process, upon request, the names of all suppliers or contractors who have been pre-qualified. Only suppliers or contractors who have been pre-qualified shall be entitled to participate further in the procurement proceedings.

(4) The procuring agency shall communicate to those suppliers or contractors who have not been pre-qualified the reasons for not pre-qualifying them.

17. Qualification of suppliers and contractors

A procuring agency, at any stage of the procurement proceedings, having credible reasons for or prima facie evidence of any defect in supplier's or contractor's capacities, may require the suppliers or contractors to provide information concerning their professional, technical, financial, legal or managerial competence whether already pre-qualified or not:

Provided that such qualification shall only be laid down after recording reasons therefor in writing. They shall form part of the records of that procurement proceeding.

18. Disqualification of suppliers and contractors

The procuring agency shall disqualify a supplier or contractor if it finds, at any time, that the information submitted by him concerning his qualification as supplier or contractor was false and materially inaccurate or incomplete.

19. Blacklisting of suppliers and contractors

The procuring agencies shall specify a mechanism and manner to permanently or temporarily bar, from participating in their respective procurement proceedings, suppliers and contractors who either consistently fail to provide satisfactory performances or are found to be indulging in corrupt or fraudulent practices. Such barring action shall be duly publicized and communicated to the Authority:

Provided that any supplier or contractor who is black listed shall be accorded adequate opportunity of being heard.

METHOD OF PROCUREMENT

20. Principal method of procurement

Save as otherwise provided hereinafter, the procuring agencies shall use open competitive bidding as the principal method of procurement of the procurement goods, services and works.

21. Open competitive bidding

*Subject to the provisions of rules 22 to 37 the procuring agencies shall engage in open competitive bidding if the cost of the object to be procured is more than the described financial limit which is applicable under sub-clause (i) of clause (b) of rule 42.

22. Submission of bids

(1) The bids shall be submitted in a sealed package or packages in such manner that the contents are fully enclosed and cannot be known until duly opened.

(2) A procuring agency shall specify the manner and method of submission and receipt of bids in an ambiguous and clear manner in the bidding documents.

23. Bidding documents

(1) Procuring agencies shall formulate precise and unambiguous bidding documents that shall be made available to the bidders immediately after the publication of the invitation to bid.

(2) For competitive bidding, whether open or limited, the bidding documents shall include the following, namely:

(a) invitation to bid;

(b) instructions to bidders;

(c) form of bid;

(d) form of contract;

**Amended vide Cabinet Division No. 5/37/2005-M-III/Admin (PPRA), Dated 13-12-2006*

(e) general or special conditions of contract;

(f) specifications and drawings of performance criteria (where applicable);

(g) list of goods or bill of quantities (where applicable);

(h) delivery time or completion schedule;

(i) qualification criteria (where applicable);

(j) bid evaluation criteria;

(k) format of all securities required (where applicable);

(l) details of standards (if any) that are to be used in assessing the quality of goods, works or services specified; and

(m) any other detail not inconsistent with these rules that the procuring agency may deem necessary.

(3) Any information, that becomes necessary for bidding or for bid evaluation, after the invitation to bid or issue of the bidding documents to the prospective bidders, shall be provided in a timely manner and on equal opportunity basis. Where notification of such change, addition, modification or deletion becomes essential, such notification shall be made in a manner similar to the original advertisement.

(4) Procuring agencies shall use standard bidding documents as and when notified by regulation by the Authority:

Provided that bidding documents already in use or procuring agencies may be retained in their respective usage to the extent they are not inconsistent with these rules, and till such time that the standard bidding documents are specified by regulations.

(5) The procuring agency shall provide a set of bidding documents to any supplier or contractor, on request and subject to payment of price, if any.

Explanation: For the purpose of this sub-rule price means the cost of printing and providing the documents only.

24. Reservations and preference

(1) Procuring agencies shall allow all prospective bidders to participate in procuring procedure without regard to nationality, except in cases which any procuring agency decides to limit such participation to national bidders only or prohibit participation of bidders of some nationalities, in accordance with the policy of Federal Government.

(2) Procuring agencies shall allow for a preference of domestic or national suppliers or contractors in accordance with the policies of the Federal Government. The magnitude of price preference to be accorded shall clearly be mentioned in the bidding documents under the bid evaluation criteria.

25. Bid security

The procuring agency may require the bidders to furnish a bid security not exceeding five percent of the bid price.

26. Bid validity

(1) A procuring agency, keeping in view the nature of procurement, shall subject the bid to a bid validity period.

(2) Bids shall be valid for the period of time specified in the bidding document.

(3) The procuring agency shall ordinarily be under an obligation to process and evaluate the bid within the stipulated bid validity period. However, under exceptional circumstances and for reason to be recorded in writing, if an extension is considered necessary, all those who have submitted their bids shall be asked to extend their respective bid validity period. Such extension shall be for not more than the period equal to the period of the original bid validity.

(4) Bidders who,

(a) agree to extension of their bid validity period shall also extend the validity of the bid bond or security for the extended period of the bid validity;

(b) agree to the procuring agency's request for extension of bid validity period shall not be permitted to change the substance of their bids; and

(c) do not agree to an extension of the bid validity period shall be allowed to withdraw their bids without forfeiture of their bid bonds or securities.

26. Extension of time for submission of bids

Where a procuring agency has already prescribed a deadline for the submission of bids and due to any reason the procuring agency finds it necessary to extend such deadline, it shall do so only after recording its reasons in writing and in equal opportunity manner. Advertisement of such extension in time shall be done in a manner similar to the original advertisement.

OPENING, EVALUATION AND REJECTION OF BIDS

28. Opening of bids

(1) The date for opening of bids and the last date for the submission of bids shall be the same. Bids shall be opened at the time specified in the bidding documents. The bids shall be opened at least thirty minutes after the deadline for submission of bids.

(2) All bids shall be opened publicly in the presence of the bidders or their representatives who may choose to present, at the time and place announced prior to the bidding. The procuring agency shall read aloud the unit price as well as the bid amount and shall record the minutes of the bid opening. All bidders in attendance shall sign an attendance sheet. All bids submitted after the time prescribed shall be rejected and returned without being opened.

29. Evaluation criteria

Procuring agencies shall formulate an appropriate evaluation criterion listing all the relevant information against which a bid is to be evaluated. Such evaluation criteria shall form an integral part of the bidding documents. Failure to provide for an unambiguous evaluation criteria in the bidding documents shall amount to mis-procurement.

30. Evaluation of bids

(1) All bids shall be evaluated in accordance with the evaluation criteria and other terms and conditions set forth in the bidding documents. Save as provided for in sub-clause (iv) of clause (c) of rule 36, no evaluation criteria shall be used for evaluation of bids that had not been specified in the bidding documents.

(2) For the purposes of comparison of bids quoted in different currencies, the price shall be converted into a single currency specified in the bidding documents. The rate of exchange shall be the selling rate, prevailing on the date of opening of bids specified in the bidding documents, as notified by the State Bank of Pakistan on that day.

(3) A bid once opened in accordance with the prescribed procedure shall be subject to only those rules, regulations and policies that in force at the time of issue of notice for invitation of bids.

31. Classification of bids

(1) No bidder shall be allowed to alter or modify his bid after the bids have been opened. However, the procuring agency may seek and accept clarifications to the bid that do not change the substance of the bid.

(2) Any request for clarification in the bid, made by the procuring agency shall invariably be in writing. The response to such request shall also be in writing.

32. Discriminatory and difficult conditions

Save as otherwise provided, no procuring agency shall introduce any condition, which discriminates between bidders or that is considered to be met with difficulty. In ascertaining the discriminatory or difficult nature of any condition reference shall be made to the ordinary practices of that trade, manufacturing, construction business or service to which that particular procurement is related.

33. Rejection of bids

(1) The procuring agency may reject all bids or proposals at any time prior to the acceptance of a bid or proposal. The procuring agency shall upon request communicate to any supplier or contractor who submitted a bid or proposal,

the grounds for its rejection of all bids or proposals, but it is not required to justify those grounds.

(2) The procuring agency shall incur no liability, solely by virtue of its invoking sub-rule (1) towards suppliers or contractors who have submitted bids or proposals.

(3) Notice of the rejection of all bids or proposals shall be given promptly to all suppliers or contractors that submitted bids or proposals.

34. Re-bidding

(1) If the procuring agency has rejected all bids under rule 33 it may call for a re-bidding.

(2) The procuring agency before invitation for re-bidding shall assess the reasons for rejection and may revise specifications, evaluation criteria or any other condition for bidders as it may deem necessary.

35. Announcement of evaluation reports

Procuring agencies shall announce the results of bid evaluation in the form of a report giving justification for acceptance or rejection of bids at least ten days prior to the award of procurement contract.

36. Procedures of open competitive bidding

Save as otherwise provided in these rules, the following procedures shall be permissible for open competitive bidding, namely:

(a) Single stage – one envelope procedure

Each bid shall comprise one single envelope containing, separately, financial proposal and technical proposal (if any). All bids received shall be opened and evaluated in the manner prescribed in the bidding document.

(b) Single stage – two envelope procedure

(i) The bid shall comprise a single package comprising two separate envelopes. Each envelope shall contain separately the financial proposal and technical proposal:

(ii) the envelopes shall be marked as "FINANCIAL PROPOSAL" and "TECHNICAL PROPOSAL" in bold and legible letters to avoid confusion;

(iii) initially, only the envelope marked as "TECHNICAL PROPOSAL" shall be opened;

(iv) the envelope marked as "FINANCIAL PROPOSAL" shall be retained in the custody of the procuring agency without being opened;

(v) the procuring agency shall evaluate the technical proposal in a manner prescribed in advance, without reference to the price and reject any proposal which does not conform to the specified requirements;

(vi) during the evaluation no amendments in the technical proposal shall be permitted;

(vii) the financial proposals of bids shall be opened publicly at a time, date and venue announced and communicated to the bidders in advance;

(viii) after the evaluation and approval of the technical proposal the procuring agency shall, at a time within the bid validity period, publicly open the financial proposals of the technically accepted bids only. The financial proposals of bids found technically non-responsive shall be returned un-opened to the respective bidders; and

(ix) the bid found to be the lowest evaluated bid shall be accepted.

(c) Two stage bidding procedure

First stage

(i) the bidders shall first submit, according to the required specifications, a technical proposal without price;

(ii) the technical proposal shall be evaluated in accordance with the specified evaluation criteria and may be discussed with the bidders regarding any deficiencies and unsatisfactory technical features;

(iii) after such discussions, all the bidders shall be permitted to revise their respective technical proposals to meet the requirements of the procuring agency;

(iv) the procuring agency may revise, delete, modify or add any aspect of the technical requirements or evaluation criteria, or it may add new requirements or criteria not inconsistent with these rules:

Provided that such revisions, deletions, modifications or additions are communicated to all the bidders equally at the time of invitation to submit final bids, and that sufficient time is allowed to the bidders to prepare their revised bids:

Provided further that such allowance of time shall not be less than fifteen days in the case of national competitive bidding and thirty days in the case of international competitive bidding;

(v) those bidders not willing to conform their respective bids to the procuring agency's technical requirements may be allowed to withdraw from the bidding without forfeiture of their bid security;

Second stage

(vi) The bidders, whose technical proposals or bids have not been rejected and who are willing to conform to their bids to the revised technical requirements of the procuring agency, shall be invited to submit a revised technical proposal along with the financial proposal;

(vii) the revised technical proposal and the financial proposal shall be opened at a time, date and venue announced and communicated to the bidders in advance; and

(viii) the revised technical proposal and the financial proposal shall be evaluated in the manner prescribed above. The bid found to be the lowest evaluated bid shall be accepted:

Provided that in setting the date for the revised technical proposal and financial proposal a procuring agency shall allow sufficient time to the bidders to incorporate the agreed upon changes in the technical proposal and prepare their financial proposals accordingly.

(d) Two stage – two envelope bidding procedure

First stage

(i) the bid shall comprise a single package containing two separate envelopes. Each envelope shall contain separately the financial proposal and technical proposal;

(ii) the envelopes shall be marked as "FINANCIAL POROPOSAL" and "TECHNICAL PROPOSAL" in bold and legible letters to avoid confusion;

(iii) initially, only the envelope marked "TECHNICAL PROPOSAL" shall be opened;

(iv) the envelope marked as "FINANCIAL PROPOSAL" shall be retained in the custody of the procuring agency without being opened;

(v) the technical proposal shall be discussed with the bidders with reference to the procuring agency's technical requirements;

(vi) those bidders willing to meet the requirements of the procuring agency shall be allowed to revise their technical proposals following these discussions;

(vii) bidders not willing to conform their technical proposal to the revised requirements of the procuring agency shall be allowed to withdraw their respective bids without forfeiture of their bid security;

Second stage

(viii) after agreement between the procuring agency and the bidders on the technical requirements, bidders who are willing to conform to the revised technical specifications and whose bids have not already been rejected shall submit a revised technical proposal and supplementary financial proposal, according to the technical requirement;

(ix) the revised technical proposal along with the original financial proposal and supplementary financial proposal shall be opened at a date, time and avenue announced in advance by the procuring agency:

Provided that in setting the date for the submission of the revised technical proposal and supplementary price proposal a procuring agency shall allow sufficient time to the bidders to incorporate the agreed upon changes in the technical proposal and to prepare the required supplementary financial proposal; and

(x) the procuring agency shall evaluate the whole proposal in accordance with the evaluation criteria and the bid found to be the lowest evaluated bid shall be accepted.

37. Conditions for the use single stage two envelope, two stage and two stage two envelope bidding procedures

Single stage one envelope bidding procedure shall ordinarily be the main open competitive bidding procedure used for most of the procurement. Other appropriate procedures of open competitive bidding shall be selected in the following circumstances, namely:

(a) single stage two envelope bidding procedures shall be used where the bids are to be evaluated on technical and financial grounds and price is taken into account after technical evaluation;

(b) two stage bidding procedure shall be adopted in large and complex contracts where technically unequal proposals are likely to be encountered or where the procuring agency is aware of its options in the market but, for a given set of performance requirements, there are two or more equally acceptable technical solutions available to the procuring agency; and

(c) two stage two envelope bidding method shall be used for procurement where alternative technical proposals are possible, such as certain type of machinery or equipment or manufacturing plant.

ACCEPTANCE OF BIDS AND AWARD OF PROCUREMENT CONTRACTS

38. Acceptance of bids

The bidder with the lowest evaluated bid, if not in conflict with any other law, rules, regulations or policy of the Federal Government, shall be awarded the procurement contract, within the original or extended period of bid validity.

39. Performance guarantee

Where needed and clearly expressed in the bidding documents, the procuring agency shall require the successful bidder to furnish a performance guarantee which shall not exceed ten percent of the contract amount.

40. Limitation on negotiations

Save as otherwise provided there shall be no negotiations with the bidder having submitted the lowest evaluated bid or with any other bidder:

Provided that the extent of negotiation permissible shall be subject to the regulations issued by the Authority.

41. Confidentiality

The procuring agency shall keep all the information regarding the bid evaluation confidential until the time of the announcement of the evaluation report in accordance with the requirements of rule 35.

42. Alternative methods of procurement

A procuring agency may utilize the following alternative methods of procurement of goods, services and works, namely:

(a) petty purchases

Procuring agencies may provide for petty purchases where the object of the procurement is below the financial limit of *twenty five thousand rupees. Such procurement shall be exempt from the requirements of bidding or quotation of prices:

Amended Vide Cabinet Division No. 5/37/2005-M-III (PPRA), dated 13-12-2006

Provided that the procuring agencies shall ensure that the procurement of petty purchases is in conformity with the principles of procurement prescribed in rule 4:

Provided further that procuring agencies convinced of the inadequacy of the financial limit prescribed for petty purchases in undertaking their respective operations may approach the Federal Government for enhancement of the same with full and proper justifications.

(b) request for quotations

A procuring agency shall engage in this method of procurement only if the following conditions exist, namely:

(i) the cost of object of procurement is below the prescribed limit of *one hundred thousand rupees:

*Provided that the respective Boards of Autonomous bodies are authorized to fix an appropriate limit for request for quotations method of procurement subject to a maximum of rupees five hundred thousand which will become financial limit under this sub-rule:

(ii) the object of the procurement has standard specifications;

(iii) minimum of three quotations have been obtained; and

(iv) the object of the procurement is purchased from the supplier offering the lowest price:

Provided that procuring agencies convinced of the inadequacy of the financial limit prescribed for request for quotations in undertaking their respective operations may approach the Federal Government for enhancement of the same with full and proper justifications;

(c) direct contracting

A procuring agency shall only engage in direct contracting if the following conditions exist, namely:

(i) the procurement concerns the acquisition of spare parts or supplementary services from original manufacturer or supplier:

**Amended vide Cabinet Division No. 5/37/2005-M-III/Admin (PPRA), Dated 13-12-2006*

Provided that the same are not available from alternative sources;

(ii) only one manufacturer or supplier exists for the required procurement:

Provided that the procuring agencies shall specify the appropriate fora, which may authorize procurement of proprietary object after due diligence; and

(iii) where a change of supplier would oblige the procuring agency to acquire material having different technical specifications or characteristics and would result in incompatibility or disproportionate technical difficulties in operation and maintenance:

Provided that the contract or contracts do not exceed three years in duration;

(iv) repeat orders not exceeding fifteen percent of the original procurement;

(v) in case of an emergency:

Provided that the procuring agencies shall specify appropriate fora vested with necessary authority to declare an emergency;

*(vi) when the price of goods, services or works is fixed by the government, or

any other authority, agency or body duly authorized by the Government, on its behalf, and

*(vii) for purchase of motor**vehicle from local original manufacturers or their authorized agents at manufacturer's price.

(d) negotiating tendering

A procuring agency may engage in negotiated tendering with one or more suppliers or contractors with or without prior publication of a procurement notification. This procedure shall only be used when,

**Amended vide Cabinet Division No. 5/37/2005-M-III/Admin (PPRA), Dated 23-09-2008*

**Amended vide Cabinet Division No. 5/37/2005-M-III/Admin (PPRA), Dated 27-01-2006*

i. the supplies involved are manufactured purely for the purpose of supporting a specific piece of research or an experiment, a study or a particular development;

ii. for technical or artistic reasons, or for reasons connected with protection of exclusive rights or intellectual property, the supplies may be manufactured or delivered only by a particular supplier;

iii. for reasons of extreme urgency brought about by events unforeseeable by the procuring agency, the time limits laid down for open and limited bidding methods cannot be met. The circumstances invoked to justify extreme urgency must not be attributable to the procuring agency:

Provided that any procuring agency desirous of using negotiated tendering as a method of procurement shall record its reasons and justifications in writing for resorting to negotiated tendering and shall place the same on record.

43. On account payments

All procuring agencies shall make prompt payments to suppliers and contractors against their invoices or running bills within the time given in the conditions of the contract, which shall not exceed thirty days.

44. Entry into force of the procurement contract

A procurement contract shall come into force,

a) where no formal signing of the contract is required, from the date the notice of the acceptance of the bid or purchase order has been given to the bidder whose bid has been accepted. Such notice of acceptance or purchase order shall be issued within a reasonable time; or

b) where the procuring agency requires signing of a written contract, from the date on which the signatures of both the procuring agency and the successful bidder are affixed to the written contract. Such affixing of signatures shall take place within a reasonable time:

Provided that where the coming into force of a contract is contingent upon fulfilment of a certain condition or conditions, the contract shall take effect from the date whereon such fulfilment takes place.

45. Closing of contract

(1) Except for defect liability or maintenance by a supplier or contractor, as specified in the conditions of a contract, performance of a contract shall be deemed close on the issue of overall delivery certificate or taking over certificate which shall be issued within thirty days of final taking over of goods or receiving the deliverables or completion of works enabling the supplier or contractor to submit final bill and the auditors to do substantial audit.

(2) In case of defect liability or maintenance period, defect liability certificate shall be issued within thirty days of the expiry of the said period enabling the supplier or contractor to submit the final bill. Except for unsettled claims, which shall be resolved through arbitration, the bill shall be paid within the time given in the conditions of the contract, which shall not exceed sixty days to close the contract for final audit.

MAINTENANCE OF RECORD AND FREEDOM OF INFORMATION

46. Record of procurement proceedings

(1) All procuring agencies shall maintain a record of their respective procurement proceedings along with all associated documentation for a minimum period of five years.

(2) Such maintenance of record shall be subject to the regulations framed in this regard from time to time.

47. Public access and transparency

As soon as a contract has been awarded, the procuring agency shall make all documents related to the evaluation of the bid and award of contract public:

Provided that where the disclosure of any information related to the award of contract is of proprietary nature or where the procuring agency is convinced that such disclosure shall be against the public interest, it can withhold only such information from public disclosure subject to the prior approval of the Authority.

REDRESSAL OF GRIEVANCES AND SETTLEMENT DISPUTES

48. Redressal of grievances by the procuring agency

(1) The procuring agency shall constitute a committee comprising of odd number of persons, with proper powers and authorizations, to address the complaints of bidders that may occur prior to the entry into force of the procurement contract.

(2) Any bidder feeling aggrieved by any act of the procuring agency after the submission of his bid may lodge a written complaint concerning his grievances not later than fifteen days after the announcement of the bid evaluation report under rule 35.

(3) The committee shall investigate and decide upon the complaint within fifteen days of the receipt of the complaint.

(4) Mere fact of lodging of a complaint shall not warrant suspension of the procurement process.

(5) Any bidder not satisfied with the decision of the committee of the procuring agency may lodge an appeal in the relevant court of jurisdiction.

49. Arbitration

(1) After coming into force of the procurement contracts, disputes between the parties to the contract shall be settled by arbitration.

(2) The procuring agencies shall provide for a method of arbitration in the procurement contract, not inconsistent with the laws of Pakistan.

50. Mis-procurement

Any unauthorized breach of these rules shall amount to mis-procurement.

51. Overriding effect

The provisions of these rules shall have effect notwithstanding anything to the contrary contained in any other rules concerning public procurements:

Provided that the prevailing rules and procedures will remain applicable only for the procurement of goods, services and works for which notice of invitation of bids has been issued prior to the commencement of these rules unless the procuring agency deems it appropriate to re-issue the notice for the said procurement after commencement of these rules.

Appendix II: Public Procurement Regulations 2008

Islamabad, the 11th July, 2008

NOTIFICATION

S.R.O. 805(I)/2008. In exercise of the powers conferred by section 27 of the Procurement Regulatory Authority Ordinance, 2002 (XXII of 2002), the Authority is pleased to make the following regulations, namely;

1. **Short title and commencement.** (1) These regulations may be called the Public Procurement Regulations, 2008.

2. **Definitions.** (1) In these regulations, unless there is anything repugnant in the subject of context,

(a) "Ordinance" means the Public Procurement Regulatory Authority Ordinance, 2002 (XXII of 2002); and

(b) "rules" means the Public Procurement Rules, 2004.

(2) The expression used but not defined herein shall have the same meaning as are assigned to them in Ordinance and rules.

3. **Bidding documents.** A procuring agency when engaged in procurement of works, shall use the standard form of bidding documents prescribed by the Pakistan Engineering Council constituted under the Pakistan Engineering Council Act, 1975 (V of 1976).

4. **Record to be kept.** A Procuring agency shall keep the following record of the procurement proceedings for at least five years from the date of completion of procurement of contract or rejection of all bids under rule 33 of the rules, namely:

(a) a brief description of the goods or works to be procured or of the procurement need for which the procuring agency requested proposal or offers;

(b) the names and addresses of suppliers or contractors that submitted bids, proposals, offers or quotations and name and address of supplier or contractor with whom the procurement contract is entered into and the contract price;

(c) the names and addresses of suppliers or contractor who were pre-qualified or selected and invited to submit bids or technical proposals;

(d) information related to the qualifications or disqualifications of suppliers or contractors who have submitted bids, proposals, offers or quotations;

(e) the price or the basis for determining the price and a summary of the other terms and conditions of each bid, proposal, offer or quotation and procurement contract stipulated by the procuring agency;

(f) evaluation report prepared under rule 35 of the rules, along with any reservation and preference under rule 24 ibid;

(g) in case of rejection of bids pursuant to rule 33 of the rules, its complete record;

(h) in case of any other method of procurement except open competitive bidding which does not culminate in procurement contract, a statement to that effect and the reasons thereof; and

(i) a summary of any requests for clarification of the pre-qualification or solicitation documents, the response thereto, as well as summary of any modification to those documents.

5. Obtaining the record. (1) After acceptance of the bids or, as the case may be, termination of the procurement proceedings without resulting in a contract, any person may, on request, obtain the records referred to in clauses (a) and (c) of regulation 4.

(2) After acceptance of the bids or, as the case may be, termination of the procurement proceedings without resulting in a contract any person who submitted bids, proposals, offers or quotations or applied for pre-qualification may obtain, on request, the records referred to in clauses (b), (d), (e), (f) and (g) of regulation 4.

(3) The record referred to in regulation 4 may also be made available within a reasonable time to the Auditor General of Pakistan or any authorized officer of the Authority or the Federal Government.

6. No liability to suppliers etc. A procuring agency shall not be liable to suppliers or contractors for damages owing solely to a failure of keeping record of the procurement proceedings in accordance with these regulations.

7. *Posting of contract awards on PPRA's Website. all procuring agencies whether within or outside Pakistan shall post Contract awards over fifty million rupees on PPRA's website on the proformas as set out in Annexure-I and Annexure-II to these regulations:

Provided that where any information is related to the award of contract is of proprietary nature or where the procuring agency is convinced that such disclosure of information shall be against the public interest, it can withhold only such information from uploading on PPRA's website Public Procurement Regulatory Authority.

**Issued Vide Cabinet Division S.R.O (I)/2009, dated 09-07-2009*

[F.No. 2/1/2008/PPRA-RA.III.]

ATTACHMENT-I

(See regulation 2)

PUBLIC PROCUREMENT REGULATORY AUTHORITY (PPRA)
CONTRACT AWARD PROFORMA-I

To Be Filled and Uploaded on PPRA Website in Respect of ALL Public Contracts of Works, Services and Goods Worth Fifty Million RUPEES or More

☐ NAME OF THE ORGANISATION/DEPTT._____

☐ FEDERAL/PROVINCIAL GOVT._____

☐ TITLE OF CONTRACT._____

☐ TENDER NUMBER._____

☐ BRIEF DESCRIPTION OF CONTRACT _____
_____
_____
_____

☐ TENDER VALUE._____

☐ ENGINEER'S ESTIMATE_____

(for civil works only)

☐ ESTIMATEDCOMPLETIONPERIOD_____

☐ WHETHER THE PROCUREMENT WAS INCLUDED IN ANNUAL PROCUREMENT PLAN?_____(Yes/No)

☐ ADVERTISEMENT:

(i) PPRA Website _____(Yes/No)

(Federal agencies) (If yes please date and PPRA's tender number)

(ii) Newspapers_____(Yes/No)

(If yes give names of newspapers and dates)

☐ TENDER OPENED ON (DATE & TIME)_____

☐ NATURE OF PURCHASE_____ Local/International

☐ EXTENSION IN DUE DATE (if any)_____Yes/No

-:2:-

- ☐ NUMBER OF TENDER DOCUMENTS SOLD_____

  (Attach list of Buyers)

- ☐ WHETHER QUALIFICATION CRITERIAWAS INCLUDED IN BIDDING/ TENDER DOCUMENTS_____Yes/No

  (If yes enclose a copy)

- ☐ WHETHER BID EVALUATION CRITERIA WAS INCLUDED IN BIDDING/ TENDER DOCUMENTS_____ Yes/No

- ☐ WHICH METHOD OF PROCUREMENT WAS USED : (Tick one)

a) SINGLE STAGE – ONE ENVELOPE PROCEDURE_____ ☐

b) SINGLE STAGE – TWO ENVELOPE PROCEDURE_____ ☐

c) TWO SATGE BIDDING PROCEDURE_____ ☐

d) TWO STAGE – TWO ENVELOPE BIDDING PROCEDURE_____ ☐

- PLEASE SPECIFY IF ANY OTHER METHOD OF PROCUREMENT WAS ADOPTED WITH BRIEF REASONS (i.e., EMERGENCY, DIRECT CONTRACTING, NEGOTIATED TENDERING, ETC.)

- WHO IS THE APPROVING AUHTORITY_____

- ☐ WHETHER APPROVAL OF COMPETENT AUTHORITY WAS OBTAINED FOR USING A METHOD OTHER THAN OPEN COMPETITIVE BIDDING.

- ☐ NUMBER OF BIDS RECEIVED_____

- ☐ WHETHER THE SUCCESSFUL BIDDER WAS LOWEST BIDDER_____ NN

- ☐ WHETHER INTEGRITY PACT WAS SIGNED_____Yes/No

ATTACHMENT-II

(See regulation 2)

PUBLIC PROCUREMENT REGULATORY AUTHORITY (PPRA)

CONTRACT AWARD PROFORMA-II

To Be Filled and Uploaded on PPRA Website in Respect of ALL Public Contracts of Works, Services & Goods Worth Fifty Million RUPEES or More

- ☐ NUMBER OF BIDDERS PRESENT AT THE TIME

  OF OPENING OF BIDS_____

- ☐ NAME AND ADDRESS OF SUCCESSFUL _____
  _____
  _____

- ☐ RANKING OF SUCCESSFUL BIDDER IN EVALUATION REPORT

  (i.e., 1ST, 2ND, 3RD EVALUATED BID)

  _____
  _____
  _____

- ☐ NEED ANALYSIS (Why the procurement was necessary?)_____
  _____
  _____
  _____

- ☐ IN CASE EXTENSION WAS MADE IN RESPONSE TIME, WHAT WERE THE REASONS (Briefly describe) _____
  _____
  _____
  _____

-:2:-

- ☐ WHETHER NAMES OF THE BIDDERS AND THEIR PRICES WERE READ OUT AT THE TIME OF OPENEING THE BIDS_____ Yes/No
- ☐ DATEOFCONTRACTSIGNING_____

  (Attach a copy of agreement)
- ☐ CONTRACTAWARDPRICE_____
- ☐ WHETHER COPY OF EVALUATION REPORT WAS GIVEN TO ALL BIDDERS_____ Yes/No

  (Attach copy of the bid evaluation report)
- ☐ ANY COMPLAINTS RECEIVED_____ Yes/No

  (If yes result thereof)

  _____
  _____
  _____
- ☐ ANY DEVIATION FROM SPECIFICATIONS GIVEN IN THE TENDER NOTICE/ DOCUMENTS_____ Yes/No

  (If yes give details)
- ☐ DEVIATION FROM QUALIFICATION CRITERIA_____ Yes/No

  (If yes give details)

_____
_____
_____

- ☐ SPECIAL CONDITIONS, IF ANY (Give Brief Description)

  _____
  _____
  _____

[F.No.2/1/2008 PPRA-RA.III]

GOVERNMENT OF PAKISTAN

CABINET SECRETARIAT

CABINET DIVISION

*****

Islamabad, the July 9, 2009

NOTIFICATION

S.R.O.(I)/2009. In exercise of the powers conferred by section 27 of the Public Procurement Regulatory Authority Ordinance, 2002 (XXII of 2002), the Public Procurement Regulatory Authority is pleased to make the following regulation, namely:

1. **Short title and commencement.-**(1) The regulations may be called the Public Procurement Regulations, 2009.

(2) They shall come into force at once.

2. Posting of contract awards on PPRA's Website. All procuring agencies whether within or outside Pakistan shall post Contract Awards over fifty million rupees on PPRA's Website on the proformas as set out in Annexure-I and Annexure-II to these regulations.

Provided that where any information is related to the award of a contract is of proprietary nature or where the procuring agency is convinced that such disclosure of information shall be against public interest, it can with hold only such information from uploading on PPRA's website subject to the prior approval of the Public Procurement Regulatory Authority.

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Appendix III: The Drugs (Labelling and Packing) Rules, 1986

1. Short title and commencement:
   (1) These rules may be called the Drugs (Labelling and Packing) Rules, 1986.
   (2) They shall come into force on the expiration of the period of one year beginning with their publication in the official Gazette.
2. Definitions: In these rules, unless there is anything repugnant in the subject, or context;
   (a) "international non-proprietary name" means the name of a drug as recommended by the World Health Organization or such other name as may be notified by the Federal Government in the Official Gazette;
   (b) "pharmacopoeia" means a publication mentioned in sub-clause (ii) of clause (z) of Section 3 of the Drugs Act, 1976 (XXXI of 1976);
   (c) "pharmacopoeial name" means the name of a drug as mentioned in the pharmacopoeia;
   (d) "Schedule" means a schedule to these rules; and
   (e) "registered medical practitioner" means a medical practitioner registered or provisionally registered under the Medical and Dental Council Ordinance, 1962 (XXXII of 1962).
3. Manner of labelling: The following particulars shall appear either in print or in writing in inedible ink in a conspicuous manner on the label of the innermost container of a drug and also on the covering in which such container is packed, namely:
   (a) the registered name of the drug;
   (b) if the registered name is a proprietary name, then immediately following the registered name, the generic name or other name, if any, approved by the Registration Board, for this purpose small be printed within brackets with at least equal prominence as that of the brand name;
   (c) the international non-proprietary name or the pharmacopoeial name or the generic name, and if no such name is known, the chemical name, of each active ingredient of a drug with weight or measure in metric system, or the number of units of activity, as the case may be, expressed:
      (i) in the case of oral liquid preparations, in terms of contents per specified volume, the volume being indicated in millilitres;
      (ii) in the case of liquid parenteral preparations ready for administration, in terms of millilitres or percentage by volume or dose:

   Provided that in the case of a preparation contained in ampoule, it shall be sufficient if the ingredients are shown on the label or warpper affixed to any package in which such ampoule is issued for sale:

(iii) in the case of drugs in solid form intended for parenteral administration, in terms of weight or unitage, per milligram or gram or per container;

(iv) in the case of tablets, capsules, pills and the like, in terms of the contents per tablets, capsule, pill or other unit, as the case may be; and

(v) in the case of other preparations, in terms of percentage by weigh or volume or unitage, per gram or millilitre, as the case may be;

(d) the name and principle place of business of the manufacturer;

(e) the drug manufacturing licence number;

(f) the drug registration number;

(g) the date of expiry;

(h) Urdu version of the following:

(i) registered name of drug;

(ii) dosage (numerals in English shall be sufficient); and

(iii) instructions.

(i) the distinctive batch number, date of manufacture and the maximum retail price:

Provided that in the case of a drug packed in a strip of paper, or blister or foil, or contained in an ampoule of a capacity of not more than two millilitres or in an ampoule containing a sterile suture or ligature, and such strip, foil, blister or ampoule is placed in another package, and also in the case of printed collapsible tubes, it shall be sufficient to give the information on the outer packing containing such strip, foil, blister or ampoule:

Provided further that the Registration Board may allow relaxation of any of these conditions.

4. Labelling of drugs for internal use: The label of container of a drug meant for internal use, except a drug contained in a strip or foil or blister or collapsible tube, shall, in addition to the particulars required to be given under rule 3, bear in a conspicuous manner:

(i) if it contains a substance specified in the Schedule, the words “To be sold on prescriptions of a registered medical practitioner only”; and

(ii) if it contains not less than three per cent by volume an alcohol, a statement giving the quantity of alcohol in terms of average percentage by volume of absolute alcohol in the finished product.

5. Labelling of drugs for external use only: The label of a container of ointment, cream, liniment, lotion, liquid, antiseptic or any other drug for external application shall, in addition to the particulars required to be given under rule 3, bear in a conspicuous manner:

(i) the words “For external use only”; and

(ii) if the drug contains a substance specified in the Schedule, the words "Poison: for external use only".

6. Labelling of physician's samples: The label of a container of every drug intended for distribution to the medical profession as free sample shall, in addition to the particulars required to be given under these rules, bear the words "Physician's sample: Not for sale" which shall be overprinted or stamped:

   Provided that if the drug is packed in a strip of paper or blister or foil or contained in an ampoule of a capacity of not more than three millilitres or in a collapsible tube, it shall be sufficient to label the outer packing only with the said words.

7. Labelling of drugs for Government supply: The label of a container of every drug intended for the supply to any Government agency, including an autonomous body or a semi-Government Agency shall, while complying with the other labelling requirements of these rules, bear the words or mark reading "Government Supply" or such other words or mark as may be required by the agency concerned.

8. Labelling of drugs for veterinary use: The label of a container of drug for veterinary use shall bear in a conspicuous manner, preferably in red ink the words for veterinary use only.

9. Outer transparent wrapper not to require labelling: Nothing in these rules shall be deemed to require the labelling of any transport cover, wrapper, case or other covering used solely for the purpose of packing, transport or delivery of a drug.

10. Labelling of non-sterile surgical ligature and suture: Every container of, and every wrapper enclosing a surgical ligature or suture, other than a ligature or suture certified to be sterile and fit for surgical use without further sterilization, shall bear a label on which shall be printed or written in a conspicuous manner in indelible red ink the word "Non-sterile surgical ligature/suture: Not to be used for operation upon human body unless properly sterilized".

11. Use of letter to indicate specifications: If a drug is included in the recent edition of any publication specified in the rules, the name of relevant publication in conventional abbreviations (B.P., U.S.P., etc.) shall be printed in indelible ink, on the label to indicate that the drug conforms to the specifications set out in that publication.

12. Packing of finished drugs: Each finished drug ready of use-shall be packed in containers intended for retail sale to a hospital, dispensary, clinic or any other such institution.

13. Labelling of drugs manufactured for export or experimental purposes:

    (1) Nothing contained in rules 3 to 12 shall apply to a drug manufactured for experimental purposes which shall be labelled in accordance with rule 23 of the Drugs (Licensing, Registering and Advertising) Rules. 1976.

(2) Labelling of drugs manufactured for export shall, in addition to meeting specific requirements of the importers, bear following particulars printed in indelible ink, on the inner most container and other packings of such drugs,

(i) name of drugs;

(ii) name and address of manufacturer; and

(iii) batch number and dates of manufacture and expiry date of the drug:

Provided that in case of a drug packed in a strip of paper, foil or blister or contained in an ampoule of a capacity of not more than two millilitres or in a printed collapsible tube or in an ampoule containing a sterile suture or ligature and that such strip, foil, blister or ampoule is placed in another package, then it shall be sufficient to give name, date of expiry and batch number of the drug, name and address of the manufacturer on the inner-most container or its label, while full particulars shall be given on outer packing containing such strip, foil, blister, ampoule or tube.

14. Exemption: These rules shall not be applicable in respect of a drug made up ready for treatment, whether after or without dilution and is supplied by a person licensed to sell drugs on the prescription of a registered medical practitioner:

Provided that the label bears the following particulars, namely:

(i) the name and address of the suppliers of the drug;

(ii) the name of the patient;

(iii) the number representing the serial number of the entries in the prescription register;

(iv) if the drug is for internal use, the dosage;

(v) if the drug is for external use, and does not contain a substance specified in the Schedule' the words "For external use only"; and

(vi) if the drug is for external use and contains a substance specified in the Schedule, the words "Poison: for external use only".

THE SCHEDULE

To be sold by a retailer on the prescription of registered medical practitioner

1. C.N.S. stimulants.
2. Drugs affecting uterine motility.
3. Drugs inhibiting hormonal production.
4. Hormones and other steroidal preparation excluding preparations for external and topical use.
5. Narcotic drugs as per Single Convention on Narcotic Drugs, 1961.
6. Psychotropic substances mentioned as per Convention on Psychotropic Substances, 1971.

Appendix IV: Standard Bidding Documents for Procurement of Contraceptives through International Competitive Bidding

Overview of Standard Bidding Documents

The Standard Bidding Document package will usually consist of the following documents:

- Instructions to Bidder
- Bid Data Sheet
- General Conditions of Contract
- Special Conditions of Contract
- Technical Specifications
- Schedule of Requirements
- Special Forms, which can include:
  - Bid Submission Form
  - Price Schedules for Contraceptives
  - Manufacturer's Authorization
  - Bid Security Forms
  - Contract Form
  - Performance Guarantees
  - Product Certification Form

Samples of these documents are included in this Appendix.

The preparation of the bidding document is the responsibility of the Procuring Unit. The bidding document shall contain sufficient information to enable competition to take place among Bidders on the basis of complete, unbiased and objective terms.

Although preparation of the bidding document is the responsibility of the Procuring Unit, it shall be prepared in close collaboration with the beneficiary and end user.

The bidding document shall furnish all information necessary for a potential Bidder to prepare a bid. The bid document shall include:

(a) instructions for the preparation and submission of bids;

(b) information concerning the last date and place(s) for receipt of bids, including the date, hour and place of the bid opening with an announcement that the Bidder or their representative(s) may attend the bid opening;

(c) bid submission sheet and sample formats for bid security, performance security and manufacturers' authorisation, where applicable;

(d) the number of copies to be submitted with the original bid;

(e) conditions of contract, general and special;

(f) specification of requirements, including time limit for delivery or completion;

(g) evidence to be provided by the Bidder to demonstrate its qualifications for purposes of post-qualification verifications to be conducted by the Procuring Entity;

(h) the period for which the bid shall remain valid;

(i) the criteria to be taken into account in the evaluation of bids and award of contract and the way in which those criteria shall be evaluated;

(j) a requirement that a Bidder shall, in the form specified in the bid documents, pledge not to engage in any corrupt, fraudulent, collusive or coercive;

(k) a statement to the effect that the Procuring Entity may reject all bids at any time prior to the acceptance of a bid;

(l) a provision for holding a pre-bid meeting with potential Bidders, where appropriate, in order to provide clarifications on the conditions of the bidding documents; and

(m) a notification in the Bid Data Sheet concerning the process to be followed by a Bidder if it wishes to make any changes to its bid.

By way of further explanation of the above Regulations, Procuring Units shall comply with the following instructions when preparing bid documents.

Bidding documents shall be so worded that they permit and encourage open competition and shall set out clearly and precisely:

- the goods to be supplied;
- the place of delivery;
- the schedule for delivery;
- the minimum performance requirements;
- the warranty requirements; and
- any other relevant terms and conditions.

In addition, the bidding documents, where appropriate, shall define the tests, standards and methods that shall be used to judge the compliance of the contraceptives to be delivered with technical specifications.

The bidding document shall specify any criteria, in addition to price, which shall be taken into account in evaluating bids and how these shall be measured or otherwise evaluated.

If bids based upon alternative designs, materials, completion schedules, payment terms, etc., are permitted, the conditions for their acceptability and the method for their evaluation shall be stated in the bidding document.

All prospective Bidders shall be provided the same information and be assured of equal opportunities to obtain additional information promptly upon request.

Notes on the Instructions to Bidders (ITB) Form

This section of the Bidding Documents provides the information necessary for Bidders to prepare and submit responsive bids that meet the Purchaser's requirements. The ITB describe the critical steps of bid submission, opening and evaluation and the award of contract.

The ITB are to be used unchanged. The Bid Data Sheet (BDS) is designed to include provisions that supplement what is included in the ITB and provide the Contract-specific details needed for the bidding and evaluation process to be properly carried out. The Bid Data Sheet is specific to each procurement and must be filled in completely by the Purchaser.

Matters governing the performance of the Supplier, payments under the Contract, and affecting the risks, rights and obligations of the parties under the Contract during actual performance are not included in the ITB, but rather in the General Conditions of Contract and/or the Special Conditions of Contract Different sections of the Bidding Documents should not overlap or duplicate the coverage of a particular topic, to avoid creating ambiguity and/or contradictions.

The ITB and BDS do not form part of the final Contract.

Instructions to Bidders

A. Introduction

1. Scope of Bid

1.1 The Purchaser, as specified in the Bid Data Sheet and in the Special Conditions of Contract (SCC), invites bids for the supply of contraceptives (as specified in the Bid Data Sheet) described in the Schedule of Requirements. The name and identification number of the Contract is provided in the Bid Data Sheet and in the SCC.

1.2 Throughout these bidding documents, the terms "writing" means any typewritten, or printed communication, including e-mail, telex, cable and facsimile transmission, and "day" means calendar day. Singular also means plural.

2. Fraud and Corruption

2.1 It is the Government of Pakistan's policy to require that bidders, suppliers and contractors and their sub-contractors observe the highest standard of ethics during the procurement and execution of such contracts. In pursuance of this policy, the follpowing terms are defined:

(a)

(i) "corrupt practice" is the offering, giving, receiving or soliciting, directly or indirectly, of anything of value to influence improperly the actions of another party;

(ii) "fraudulent practice" is any act or omission, including a misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain a financial or other benefit or to avoid an obligation;

(iii) "collusive practice" is an arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another party;

(iv) "coercive practice" is impairing or harming, or threatening to impair or harm, directly or indirectly, any party or the property of the party to influence improperly the actions of a party;

(v) "obstructive practice" is

(a) deliberately destroying, falsifying, altering or concealing of evidence material to the investigation or making false statements to investigators in order to materially impede a Bank investigation into allegations of a corrupt, fraudulent, coercive or collusive practice; and/or threatening, harassing or intimidating any party to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation; or

(b) the Purchaser will reject a proposal for award if it determines that the bidder recommended for award has, directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for the contract in question;

(c) the Purchaser will sanction a firm or individual, including declaring ineligible, either indefinitely or for a stated period of time, to be awarded a contract if it, at any time, determines that the firm has, directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for, or in executing, the contract; and

(d) the Purchaser will have the right to require that a provision be included in bidding documents requiring bidders, suppliers and contractors and their sub-contractors to permit the Purchaser to inspect their accounts and records and other documents relating to the bid submission and contract performance and to have them audited by auditors appointed by the Purchaser.

2.2 Furthermore, bidders shall be aware of the provision stated in Sub-Clauses 5.4 and 23.1 (d) of the General Conditions of Contract.

3. Eligibility

3.1 Except as provided in ITB Sub-Clauses 3.2 and 3.3, this bidding process is open to qualified (prequalified or not) firms from any country;

3.2 Firms of a country may be excluded from bidding if:

(a) as a matter of law or official regulation, the Government of Pakistan prohibits commercial relations with that country;

(b) government-owned enterprises in Pakistan may participate only if they can establish that they (i) are legally and financially autonomous sand (ii) operate under commercial law.

3.3 A firm declared ineligible by the Government of Pakistan shall be ineligible to bid for a contract during the period of time determined by the Government of Pakistan.

3.4 A firm that has been determined to be ineligible by the Government of Pakistan in relation to the Guidelines on Preventing and Combating Fraud and Corruption shall be not be eligible to be awarded a contract.

4. Documents Establishing Conformity to Bidding Documents

4.1 The documentary evidence of conformity of the contraceptives to the Bidding Documents may be in the form of literature, drawings and data and shall consist of:

(a) a detailed description of the essential technical and performance characteristics of the contraceptives;

(b) an item-by-item commentary on the Purchaser's Technical Specifications demonstrating substantial responsiveness of the contraceptives to those

specifications, or a statement of deviations and exceptions to the provisions of the Technical Specifications;

(c) any other procurement-specific documentation requirement as stated in the Bid Data Sheet.

4.2 Unless the Bid Data Sheet stipulates otherwise, the contraceptives to be supplied under the Contract shall be registered with the Drug Control Authority of Pakistan, as required. A Bidder who has already registered its contraceptives by the time of bidding should submit a copy of the Registration Certificate with its bid. Otherwise, the successful Bidder, by the time of Contract signing, shall submit to the Purchaser either:

(a) a copy of the Registration Certificate of the contraceptives for use in the Purchaser's country.

OR, if such Registration Certificate has not yet been obtained,

(b) evidence establishing to the Purchaser's satisfaction that the Bidder has complied with all the documentary requirements for registration as specified in the Bid Data Sheet.

4.2.1 The Purchaser shall at all times cooperate with the successful Bidder to facilitate the registration process within the Purchaser's country. The agency and contact person able to provide additional information about registration are identified in the Bid Data Sheet.

4.2.2 If the contraceptives of the successful Bidder have not been registered in the Purchaser's country at the time of Contract signing, then the Contract shall become effective upon such date as the Certificate of Registration is obtained.

4.3 For purposes of the commentary to be furnished pursuant to ITB Clause 6.3 (b) above, the Bidder shall note that standards as well as references to brand names designated by the Purchaser in its Technical Specifications are intended to be descriptive only and not restrictive. The Bidder may substitute alternative standards, brand names, and/or catalogue numbers in its bid, provided that it demonstrates to the Purchaser's satisfaction that the substitutions ensure substantial equivalence to those designated in the Technical Specifications.

5. Qualifications of the Bidder

5.1 The Bidder shall provide documentary evidence to establish to the Purchaser's satisfaction that:

(a) the Bidder has the financial, technical, and production capability necessary to perform the Contract, meets the qualification criteria specified in the Bid Data Sheet, and has a successful performance history in accordance with criteria specified in the Bid Data Sheet. If a prequalification process has been undertaken

for the Contract, the Bidder shall, as part of its bid, update any information submitted with its application for prequalification.

(b) in the case of a Bidder offering to supply contraceptives, identified in the Bid Data Sheet, that the Bidder did not manufacture or otherwise produce, the Bidder has been duly authorized by the manufacturer or producer of such contraceptives to supply the contraceptives in the Purchaser's country;

(c) in the case of a Bidder who is not doing business within the Purchaser's country (or for other reasons will not itself carry out service/maintenance obligations), the Bidder is or will be (if awarded the Contract) represented by a local service/maintenance provider in the Purchaser's country equipped and able to carry out the Bidder's warranty obligations prescribed in the Conditions of Contract and/or Technical Specifications; and

(d) the Bidder meets the qualification criteria listed in the Bid Data Sheet (see additional clauses of Bid Data Sheet for pharmaceuticals and vaccines).

6. One Bid per Bidder

6.1 A firm shall submit only one bid either individually or as a partner of a joint venture (other than in cases of alternatives pursuant to ITB Clause 18). A firm that submits either individually or, as a member of a joint venture, more than one bid will cause all the proposals with the firm's participation to be disqualified.

7. Cost of Bidding

7.1 The Bidder shall bear all costs associated with the preparation and submission of its bid, and the Purchaser will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the bidding process.

B. The Bidding Documents

8. Content of Bidding Documents

8.1 The Bidding Documents are those stated below and should be read in conjunction with any addendum issued in accordance with ITB Clause 10.

Section I. Instructions to Bidders (ITB)
Section II. Bid Data Sheet (BDS)
Section III Eligibility
Section IV. General Conditions of Contract (GCC)
Section V. Special Conditions of Contract (SCC)
Section VI. Schedule of Requirements
Section VII. Technical Specifications
Section VIII. Sample Forms (including Contract Agreement)

8.2 The "Invitation for Bids" does not form part of the Bidding Documents and is included as a reference only. In case of discrepancies between the Invitation for Bid

and the Bidding Documents listed in 8.1 above, said Bidding Documents will take precedence.

9. Clarification of Bidding Documents

9.1 A prospective Bidder requiring any clarification of the Bidding Documents shall contact the Purchaser in writing or by cable (for these ITB, the term "cable" is deemed to include electronic mail, telex, or facsimile) at the Purchaser's address indicated in the Bid Data Sheet. The Purchaser will respond ***in writing to any request for clarification received no later than fourteen (14) calendar days*** prior to the deadline of submission of bids. Copies of the Purchaser's response shall be sent to all prospective Bidders who have purchased the Bidding Documents, including a description of the inquiry but without identifying its source.

10. Amendment of Bidding Documents

10.1 At any time prior to the deadline for submission of bids, the Purchaser may amend the Bidding Documents by issuing Addenda.

10.2 Any addendum thus issued shall be part of the Bidding Documents pursuant to ITB Sub-Clause 8.1 and shall be communicated in writing to all purchasers of the Bidding Documents and will be binding on them. Bidders are required to immediately acknowledge receipt of any such amendment, and it will be assumed that the information contained in the amendment will have been taken into account by the Bidder in its bid.

10.3 To give prospective Bidders reasonable time in which to take the amendment into account in preparing their bids, the Purchaser shall extend, at its discretion, the deadline for submission of bids, in which case, the Purchaser will notify all Bidders by cable confirmed in writing of the extended deadline.

C. Preparation of Bids

11. Language of Bid

11.1 The bid, as well as all correspondence and documents relating to the bid exchanged by the Bidder and the Purchaser, shall be written in the language specified in the Bid Data Sheet. Supporting documents and printed literature furnished by the Bidder may be in another language provided they are accompanied by an accurate translation of the relevant passages in the language specified, in which case, for purposes of interpretation of the Bid, the translation shall govern.

12. Documents Constituting the Bid

12.1 The bid submitted by the Bidder shall comprise the following:

(a) duly filled-in Form of Bid and Price Schedule, in accordance with the forms indicated in Section VIII;

(b) original form of bid security in accordance with the provisions of ITB Sub-Clause 19 (Bid Security);

(c) alternative offers, at the Bidder's option, when permitted;

(d) written power of attorney authorizing the signatory of the bid to commit the Bidder;

(e) documentary evidence establishing to the Purchaser's satisfaction, and in accordance with ITB Clause 5 that the Bidder is qualified to perform the Contract if its bid is accepted. In the case where prequalification of Bidders has been undertaken, and pursuant to ITB Paragraph 5.1(a), the Bidder must provide evidence on any changes in the information submitted as the basis for prequalification, or if there has been no change at all in said information, a statement to this effect;

(f) any other documentation as requested in the Bid Data Sheet.

13. Bid Form

13.1 The Bidder shall complete the Bid Form and the appropriate Price Schedule furnished in the Bidding Documents, indicating the contraceptives to be supplied, a brief description of the contraceptives, their country of origin, quantity and prices.

13.2 For the purpose of granting a margin of domestic preference, bids will be classified in one of three groups, as follows:

(a) Group A: Bids offering contraceptives manufactured in the Purchaser's country, for which (i) labor, raw materials, and components from within the Purchaser's country account for more than thirty (30) percent of the EXW price; and (ii) the production facility in which they will be produced or manufactured has been engaged in producing or manufacturing such contraceptives at least since the date of bid submission.

(b) Group B: All other bids offering contraceptives from within the country of the Purchaser.

(c) Group C**:** Bids offering contraceptives of foreign origin already imported or to be imported by the Purchaser directly or through the Supplier's local agent.

13.3 To facilitate this classification by the Purchaser, the Bidder shall complete whichever version of the Price Schedule furnished in the Bidding Documents is appropriate, provided the completion of an incorrect version of the Price Schedule by the Bidder will not result in rejection of its bid, but merely in the Purchaser's reclassification of the bid into its appropriate bid group.

14. Bid Prices

14.1 Prices shall be quoted as specified in each Price Schedule included in Section VIII, Sample Forms. The disaggregation of price components is required solely for the purpose of facilitating the comparison of bids by the Purchaser. This shall not in any way limit the Purchaser's right to contract on any of the terms offered.

14.2 Prices shall be entered in the following manner:

(a) For contraceptives manufactured in the Purchaser's Country:

(i) the price of the contraceptives quoted EXW (ex works, ex factory, ex warehouse, ex showroom, or off-the-shelf, as applicable), including all customs duties and sales and other taxes already paid or payable on the components and raw material used in the manufacture or assembly of the contraceptives;

(ii) any Purchaser's Country sales tax and other taxes which will be payable on the contraceptives if the contract is awarded to the Bidder; and

(iii) the price for inland transportation, insurance and other local services required to convey the contraceptives to their final destination specified in the Bid Data Sheet.

(b) For contraceptives manufactured outside the Purchaser's Country, to be imported:

(i) the price of the contraceptives, quoted CIP named place of destination, in the Purchaser's Country, or CIF named port of destination, as specified in the Bid Data Sheet;

(ii) the price for inland transportation, insurance and other local services required to convey the contraceptives from the named place of destination to their final destination specified in the Bid Data Sheet;

(iii) in addition to the CIP prices specified in (b)(i) above, the price of the contraceptives to be imported may be quoted FCA (named place of destination) or CPT (named place of destination), if so specified in the Bid Data Sheet;

(c) For contraceptives manufactured outside the Purchaser's Country, already imported:

[For previously imported contraceptives, the quoted CIP price shall be distinguishable from the original import value of these contraceptives declared to customs and shall include any rebate or mark-up of the local agent or representative and all local costs except import duties and taxes, which have been and/or have to be paid by the Purchaser. For clarity, the bidders are asked to quote the price including import duties, and additionally to provide the import duties and the CIP price which is the difference of those values.]

(i) the price of the contraceptives, including the original import value of the contraceptives; plus any mark-up (or rebate); plus any other related local cost, and custom duties and other import taxes already paid or to be paid on the contraceptives already imported.

(ii) the custom duties and other import taxes already paid (need to be supported with documentary evidence) or to be paid on the contraceptives already imported;

(iii) the price of the contraceptives, quoted CIP named place of destination, in the Purchaser's country obtained as the difference between (i) and (ii) above;

(iv) any Purchaser's country sales and other taxes which will be payable on the contraceptives if the contract is awarded to the Bidder; and

(v) the price for inland transportation, insurance and other local services required to convey the contraceptives from the named place of destination to their final destination specified in the Bid Data Sheet.

(d) for Related Services, other than inland transportation and other services required to convey the contraceptives to their final destination, whenever such Related Services are specified in the Schedule of Requirements:

(i) the price of each item comprising the Related Services (inclusive of any applicable taxes).

14.3 The terms EXW, CIF, CIP, etc., shall be governed by the rules prescribed in the current edition of INCOTERMS published by the International Chamber of Commerce, Paris.

14.4 The Bidder's separation of price components in accordance with ITB Clause 14.2 above will be solely for the purpose of facilitating the comparison of bids by the Purchaser and will not in any way limit the Purchaser's right to contract on any of the terms offered.

14.5 Unless otherwise specified in the Bid Data Sheet, prices quoted by the Bidder shall be fixed during the Bidder's performance of the Contract and not subject to variation on any account. A bid submitted with an adjustable price quotation will be treated as non-responsive and will be rejected, pursuant to ITB Clause 27. If, however, in accordance with the Bid Data Sheet, prices quoted by the Bidder shall be subject to adjustment during the performance of the Contract, a bid submitted with a fixed price quotation will not be rejected, but the price will not be adjusted.

14.6 Pursuant to Sub-Clause 14.1 above, and if so indicated in the Bid Data Sheet, bids are being invited for one or more items, or for individual Contracts (lots) each comprising at least eighty percent (80%) of the total number of items required under the lot. In both cases, each item offered must comprise the full quantity required under that item. Bidders wishing to offer any price reduction for the award of more than one Contract shall specify in their bid the price reductions applicable to each package or, alternatively, to individual Contracts within the package. Price reductions may be submitted as an amount or a percentage to be applied to the bid prices.

15. Currencies of Bid

15.1 Prices shall be quoted in the following currencies:

(a) The Bidder may express the bid price of the contraceptives to be supplied from outside the Purchaser's Country entirely in the currency or currencies of Bank member countries. If the Bidder wishes to be paid in a combination of different currencies, it must quote its price accordingly, but no more than three foreign currencies may be used.

(b) Unless otherwise specified in the Bid Data Sheet, the Bidder shall express its prices for such contraceptives to be supplied from within the Purchaser's country in the currency of the country of the borrower.

16. Period of Validity of Bids

16.1 Bids shall remain valid for the period stipulated in the Bid Data Sheet after the date of bid submission specified in ITB Clause 21. A bid valid for a shorter period shall be rejected by the Purchaser as nonresponsive.

16.2 In exceptional circumstances, prior to expiry of the original bid validity period, the Purchaser may request that the Bidders extend the period of validity for a specified additional period. The request and the responses thereto shall be made in writing. A Bidder may refuse the request without forfeiting its bid security. Except as provided in ITB Clause 16.3, a Bidder agreeing to the request will not be required or permitted to modify its bid, but will be required to extend the validity of its bid security for the period of the extension.

16.3 In the case of fixed price contracts, if the award is delayed by a period exceeding fifty-six (56) days beyond the expiry of the first bid validity extension, the contract price will be increased by a factor that reflects changes in the cost of inputs specified in the request for second and subsequent extensions.

17. Bid Security

17.1 If required, in the Bid Data Sheet, the Bidder shall furnish, as part of its bid, a bid security as specified in the Bid Data Sheet, or a Bid Securing Declaration. The amount of the Bid Security shall be as stipulated in the Bid Data Sheet in the currency of the Purchaser's country, or the equivalent amount in a freely convertible currency.

17.2 The bid security shall remain valid for a period of 28 days beyond the validity period for the bid, and beyond any extension subsequently requested under Sub-clause 16.2.

17.3 The bid security shall, at the Bidder's option, be in the form of either a letter of credit or a bank guarantee from a reputable banking institution, or a bond issued by a surety selected by the Bidder and located in any country. If the institution issuing the bond is located outside the purchaser's country, it shall have a correspondent

financial institution located in the purchaser's country to make it enforceable. The format of the bank guarantee/bond shall be in accordance with the forms included in the bidding documents; other formats may be permitted, subject to the prior approval of the Purchaser.

17.4 Any bid not accompanied by an acceptable bid security shall be rejected by the Purchaser as non-responsive. The bid security of a joint venture must be in the name of the joint venture submitting the bid.

17.5 The bid securities of unsuccessful Bidders will be returned as promptly as possible.

17.6 The bid security of the successful Bidder will be returned when the Bidder has signed the Contract and furnished the required performance security.

17.7 The bid security may be forfeited:

(a) if the Bidder withdraws its bid, except as provided in ITB Sub-Clauses 16.2 and 23.3; or

(b) in the case of a successful bidder, if the Bidder fails within the specified time limit to:

(i) sign the contract; or

(ii) furnish the required performance security.

17.8 If a bid security is *not required* in the BDS, and

(a) if a Bidder withdraws its bid during the period of bid validity specified by the Bidder on the Letter of Bid Form, except as provided in ITB 16.2, or

(b) if the successful Bidder fails to sign the Contract in accordance with ITB 37, or furnish a performance security in accordance with ITB 38, the Borrower may, *if provided for in the BDS,* declare the Bidder disqualified to be awarded a contract by the Employer for a period of time *as stated in the BDS.*

18. Alternative Bids by Bidders

18.1 Unless specified in the Bid Data Sheet, alternative bids shall not be accepted.

19. Format and Signing of Bid

19.1 The Bidder shall prepare an original and the number of copies/sets of the bid indicated in the Bid Data Sheet, clearly marking each one as "ORIGINAL BID" and "COPY OF BID," as appropriate. In the event of any discrepancy between them, the original shall govern.

19.2 The original and all copies of the bid, each consisting of the documents listed in ITB Sub-Clause 12.1, shall be typed or written in indelible ink and shall be signed by the Bidder or a person or persons duly authorized to bind the Bidder to the Contract. The later authorization shall be indicated by written power of attorney, which pursuant to ITB Sub-Clause 12.1 (d) shall accompany the bid.

19.3 Any interlineation, erasures, or overwriting to correct errors made by the Bidder should be initialed by the person or persons signing the bid.

19.4 The Bidder shall furnish in the Bid Form (a sample of which is provided in the Sample Forms Section of the Bidding Documents) information regarding commissions or gratuities, if any, paid or to be paid to agents relating to this bid and to the execution of the Contract if the Bidder is awarded the Contract.

D. Submission of Bids

20. Sealing and Marking of Bids

20.1 Bidders may always submit their bids by mail or by hand. When so specified in the Bid Data Sheet, bidders shall have the option of submitting their bids electronically.

(a) The Bidder shall enclose the original and each copy of the bid, including alternative bids if permitted in accordance with ITB Clause 18, in separate sealed envelopes, duly marking the envelopes as "ORIGINAL" and "COPY". The envelopes containing the original and copies shall then be enclosed in another envelope.

(b) Bidders submitting bids electronically shall follow the electronic bid submission procedures specified in the Bid Data Sheet.

20.2 The inner and outer envelopes shall:

(a) bear the name and address of the Bidder;

(b) be addressed to the Purchaser at the address given in the Bid Data Sheet;

(c) bear the specific identification of this bidding process indicated in the Bid Data Sheet, the Invitation for Bids (IFB) title and number indicated in the Bid Data Sheet; and

(d) bear a statement "DO NOT OPEN BEFORE [date and time]" to be completed with the time and date specified in the Bid Data Sheet relating to ITB Sub-Clause 21.1.

20.3 If the outer envelope is not sealed and marked as required by ITB Sub-Clause 20.2, the Purchaser will assume no responsibility for the misplacement or premature opening of the bid.

21. Deadline for Submission of Bids

21.1 Bids must be received by the Purchaser at the address specified in the Bid Data Sheet relating to ITB Sub-Clause 20.2 (b) no later than the time and date specified in the Bid Data Sheet.

21.2 The Purchaser may, at its discretion, extend the deadline for the submission of bids by amending the Bidding Documents in accordance with ITB Sub-Clause 10.3,

in which case all rights and obligations of the Purchaser and Bidders previously subject to the deadline will thereafter be subject to the deadline as extended.

22. Late Bids

22.1 Any bid received by the Purchaser after the deadline for submission of bids prescribed by the Purchaser in the Bid Data Sheet pursuant to ITB Clause 21 will be rejected and returned unopened to the Bidder.

23. Modification and Withdrawal of Bids

23.1 The Bidder may modify or withdraw its bid after submission, provided that written notice of the modification, or withdrawal of the bids duly signed by an authorized representative, is received by the Purchaser prior to the deadline prescribed for submission of bids.

23.2 The Bidder's modification shall be prepared, sealed, marked and dispatched as follows:

(a) The Bidder shall provide an original and the number of copies specified in the Bid Data Sheet of any modifications to its bid, clearly identified as such, in two inner envelopes duly marked "BID MODIFICATION-ORIGINAL" and "BID MODIFICATION-COPIES". The inner envelopes shall be sealed in an outer envelope which shall be duly marked "BID MODIFICATION".

(b) Other provisions concerning the marking and dispatch of bid modifications shall be in accordance with ITB Sub-Clauses 22.2 and 22.3.

23.3 A Bidder wishing to withdraw its bid shall notify the Purchaser in writing prior to the deadline prescribed for bid submission. A withdrawal notice shall be received prior to the deadline for submission of bids. The notice of withdrawal shall:

(a) be addressed to the Purchaser at the address named in the Bid Data Sheet,

(b) bear the specific identification of the bidding process (Contract name), the IFB title and IFB number, and the words "BID WITHDRAWAL NOTICE," and

(c) be accompanied by a written power of attorney authorizing the signatory of the withdrawal notice to withdraw the bid.

23.4 Bids requested to be withdrawn in accordance with ITB Sub-Clause 23.3, shall be returned unopened to the Bidders.

23.5 No bid may be withdrawn in the interval between the bid submission deadline and the expiration of the bid validity period specified in ITB Clause 16. Withdrawal of a bid during this interval may result in the forfeiture of the Bidder's bid security, pursuant to ITB Sub-Clause 17.7.

E. Opening and Evaluation of Bids

24. Bid Opening

24.1 The Purchaser will open all bids, including withdrawal notices and modifications, in public, in the presence of Bidders' representatives who choose to attend at the time, on the date and at the place specified in the Bid Data Sheet. Any specific electronic bid opening procedures required if electronic bidding is permitted in accordance with ITB Clause 20.1, shall be as specified in the Bid Data Sheet. Bidders' representatives shall sign a register as proof of their attendance.

24.2 Envelopes marked "WITHDRAWAL" shall be read out and the envelope with the corresponding bid shall not be opened but returned to the Bidder. No bid withdrawal notice shall be permitted unless the corresponding withdrawal notice is read out at bid opening. Envelopes marked "MODIFICATION" shall be read out and opened with the corresponding bid.

24.3 Bids shall be opened one at a time, reading out: the name of the Bidder and whether there is a modification; the bid price of each item or lot, as the case may be, including discounts and alternative offers, if allowed in the Bid Data Sheet; the presence or absence of a bid security, if required; the presence or absence of requisite powers of attorney; and any other such details as the Purchaser may consider appropriate. No bid shall be rejected at bid opening except for late bids pursuant to Sub-Clause 22.1.

24.4 Bids (and modifications sent pursuant to ITB Sub-Clause 23.2) that are not opened and read out at bid opening shall not be considered further for evaluation, irrespective of the circumstances.

24.5 The Purchaser will prepare minutes of the bid opening at the end of the opening session, including, as a minimum: the name of the Bidder and whether there was a withdrawal or modification; the bid price; including any discounts or alternatives offered if permitted in the Bid Data Sheet; the presence or absence of a bid security; the presence or absence of requisite powers of attorney.

24.6 The Bidder's representatives who are present shall be requested to sign the minutes. The omission of a Bidder's signature on the minutes shall not invalidate the content and effect of the minutes. The minutes should be distributed to all Bidders who request them.

25. Clarification of Bids

25.1 During evaluation of the bids, the Purchaser may, at its discretion, ask the Bidder for a clarification of its bid. The request for clarification and the response shall be in writing, and no change in the prices or substance of the bid shall be sought, offered or permitted, except to correct arithmetic errors identified by the Purchaser in the evaluation of the bids, in accordance with ITB Sub-Clause 28.1.

26. Confidentiality

26.1 Information relating to the examination, clarification, evaluation and comparison of bids, and recommendations for the award of a Contract shall not be disclosed to bidders or any other persons not officially concerned with such process until the notification of Contract award is made to all Bidders.

26.2 Any effort by the bidder to influence the Purchaser in the Purchaser's bid evaluation, bid comparison or contract award decisions may result in the rejection of the Bidder's bid.

26.3 From the time of bid opening to the time of Contract award, if any Bidder wishes to contact the Purchaser on any matter related to its bid, it should do so in writing.

27. Examination of Bids and Determination of Responsiveness

27.1 The Purchaser will examine the bids to determine whether they are complete, whether any computational errors have been made, whether required sureties have been furnished, whether the documents have been properly signed and whether the bids are generally in order. In the case where a pre-qualification process has been undertaken for the Contract(s) for which these Bidding Documents have been issued, the Purchaser will ensure that each bid is from a prequalified Bidder.

27.2 The Purchaser may waive any minor informality, nonconformity or irregularity in a bid that does not constitute a material deviation, provided such waiver does not prejudice or affect the relative ranking of any Bidder.

27.3 Prior to the detailed evaluation, pursuant to ITB Clause 30, the Purchaser will determine whether each bid is of acceptable quality, is complete and is substantially responsive to the Bidding Documents. For purposes of this determination, a substantially responsive bid is one that conforms to all the terms, conditions, and specifications of the Bidding Documents without material deviations, exceptions, objections, conditionalities, or reservations. A material deviation, exception, objection, conditionality, or reservation is one: (i) that limits in any substantial way the scope, quality or performance of the contraceptives and related Services; (ii) that limits, in any substantial way that is inconsistent with the Bidding Documents, the Purchaser's rights or the successful Bidder's obligations under the Contract; and (iii) that the acceptance of which would unfairly affect the competitive position of other Bidders who have submitted substantially responsive bids.

27.4 If a bid is not substantially responsive, it will be rejected by the Purchaser and may not subsequently be made responsive by the Bidder by correction of the nonconformity. The Purchaser's determination of a bid's responsiveness is to be based on the contents of the bid itself.

28. Correction of Errors

28.1 Arithmetical errors will be rectified as follows. If there is a discrepancy between the unit price and the total price that is obtained by multiplying the unit price

and quantity, the unit or subtotal price shall prevail. If there is a discrepancy between subtotals and the total price, the total price shall be corrected. If there is a discrepancy between words and figures, the amount in words will prevail. If a Bidder does not accept the correction of errors, its bid will be rejected.

29. Conversion to Single Currency

29.1 To facilitate evaluation and comparison, the Purchaser will convert all bid prices expressed in the various currencies in which they are payable to either:

(a) the currency of the Purchaser's country at the selling exchange rate established for similar transactions by the Central Bank or a commercial bank in the Purchaser's country.

or

(b) a currency widely used in international trade, such as U.S. dollars, at the selling rate of exchange published in the international press for the amount payable in foreign currency; and at the selling exchange rate established for similar transactions by the Central Bank in the Purchaser's country for the amount payable in the currency of the Purchaser's country.

29.2 The currency selected for converting bid prices to a common base for the purpose of evaluation, along with the source and date of the exchange rate, are specified in the Bid Data Sheet.

30. Evaluation and Comparison of Bids

30.1 The Purchaser will evaluate and compare the bids that have been determined to be substantially responsive, pursuant to ITB Clause 27.

30.2 The Purchaser's evaluation of a bid will exclude and not take into account:

(a) in the case of contraceptives manufactured in the Purchaser's country or contraceptives of foreign origin already located in the Purchaser's country, sales and other similar taxes that will be payable on the contraceptives if a contract is awarded to the Bidder;

(b) in the case of contraceptives of foreign origin already imported and to be imported from abroad, customs duties and other similar import taxes paid or payable on the contraceptives if the contract is awarded to the Bidder; and

(c) any allowance for price adjustment during the period of execution of the Contract, if provided in the bid.

30.3 The comparison shall be between the EXW price of the contraceptives offered from within the Purchaser's country plus local transportation, such price to include all costs, as well as duties and taxes paid or payable on components and raw material incorporated or to be incorporated in the contraceptives, and the CIF named port of destination (or CIP border point, or CIP named place of destination)

price of the contraceptives offered from outside the Purchaser's country, plus local transportation.

30.4 The Purchaser's evaluation of a bid will take into account, in addition to the bid price quoted in accordance with ITB Sub-Clause 16.2, one or more of the following factors as specified in the BDS, and quantified in ITB Sub-Clause 32.5:

(a) delivery schedule offered in the bid;

(b) deviations in payment schedule from that specified in the Special Conditions of Contract;

(c) other specific criteria indicated in the Bid Data Sheet and/or in the Technical Specifications.

30.5 For factors retained in the Bid Data Sheet pursuant to ITB Sub-Clause 30.4, one or more of the following quantification methods will be applied, as detailed in the Bid Data Sheet:

(a) Delivery schedule.

(i) The Purchaser requires that the contraceptives under these Bidding Documents shall be delivered (shipped) at the time specified in the Schedule of Requirements. The estimated time of arrival of the contraceptives at the site will be calculated for each bid after allowing for reasonable international and inland transportation time. A delivery "adjustment" will be calculated for and added to each bid by applying a percentage, specified in the Bid Data Sheet, of the EXW/CIF/CIP price for each week of delay beyond the expected time of arrival specified in the Bidding Documents for evaluation purposes. No credit shall be given to early delivery.

or

(ii) The contraceptives covered under these Bidding Documents are required to be delivered (shipped) within an acceptable range of weeks specified in the Schedule of Requirements. No credit will be given to earlier deliveries, and bids offering delivery beyond this range will be treated as nonresponsive. Within this acceptable range, an adjustment per week, as specified in the Bid Data Sheet, will be added for evaluation to the bid price of bids offering deliveries later than the earliest delivery period specified in the Schedule of Requirements.

or

(iii)The contraceptives covered under this invitation are required to be delivered (shipped) in partial shipments, as specified in the Schedule of Requirements. Bids offering deliveries earlier or later than the specified deliveries will be adjusted in the evaluation by adding to the bid price a factor equal to

a percentage, specified in the Bid Data Sheet, of EXW/CIF/CIP price per week of variation from the specified delivery schedule.

(b) Deviation in payment schedule.

(i) Bidders shall state their bid price for the payment schedule outlined in the SCC. Bids will be evaluated on the basis of this base price. Bidders are, however, permitted to state an alternative payment schedule and indicate the reduction in bid price they wish to offer for such alternative payment schedule. The Purchaser may consider the alternative payment schedule offered by the selected Bidder.

or

(ii) The SCC stipulate the payment schedule offered by the Purchaser. If a bid deviates from the schedule and if such deviation is permitted in the Bid Data Sheet, the bid will be evaluated by calculating interest earned for any earlier payments involved in the terms outlined in the bid as compared with those stipulated in this invitation, at the rate per annum specified in the Bid Data Sheet.

(c) Other specific additional criteria to be considered in the evaluation and the evaluation method shall be detailed in the Bid Data Sheet and/or in the Technical Specifications.

31. Domestic Preference

31.1 If indicated in the Bid Data Sheet and for the purpose of bid comparison, the Purchaser will grant a margin of preference to contraceptives manufactured in the Purchaser's country. This margin of preference will be granted in accordance with the procedures outlined in subsequent paragraphs, provided the Bidder shall have established to the satisfaction of the Purchaser and of the Bank that its bid complies with the criteria specified in ITB Paragraph 13.2 (a).

31.2 The Purchaser will first review the bids to confirm the appropriateness of, and to modify if necessary, the bid group classification to which Bidders assigned their bids in preparing their Bid Forms and Price Schedules.

31.3 All evaluated bids in each group will then be compared among themselves to determine the lowest evaluated bid of each group. The lowest evaluated bid of each group will next be compared with the lowest evaluated bids of the other groups. If this comparison results in a bid from Group A or Group B being the lowest, it will be selected for Contract award.

31.4 If, as a result of the preceding comparison, the lowest evaluated bid is from Group C, all Group C bids will then be further compared with the lowest evaluated bid from Group A, after adding to the evaluated bid price of the imported contraceptives offered in each Group C bid, for the purpose of this further comparison only, a flat

rate of fifteen (15) percent of the CIF (or CIP border point or CIP named place of destination, as the case may be) bid price of such contraceptives.

Domestic preference will be applied only to those items indicated in the Schedule of Requirements that meet the criteria under Paragraph 15.2 (a).

If the Group A bid in the further comparison is the lowest, it will be selected for award. If not, the lowest evaluated bid from Group C, as determined from the comparison under ITB Sub-Clause 31.3 above, will be selected for award.

F. Award of Contract

32. Post-qualification

32.1 In the absence of pre-qualification, the Purchaser will determine to its satisfaction whether the Bidder that is selected as having submitted the lowest evaluated responsive bid is qualified to perform the Contract satisfactorily, in accordance with the criteria listed in ITB Sub-Clause 5.1 and any additional postqualification criteria stated in the Bid Data Sheet. If a pre-qualification process was undertaken for the Contract(s) for which these Bidding Documents were issued, the Purchaser will determine in the manner described above that no material changes have occurred after the pre-qualification that negatively affect the ability of the Bidder that has submitted the lowest evaluated bid to perform the Contract.

32.2 The determination will evaluate the Bidder's financial, technical and production capabilities. It will be based on an examination of the documentary evidence of the Bidder's qualifications submitted by the Bidder, pursuant to ITB Sub-Clause 5.1, as well as other information the Purchaser deems necessary and appropriate.

32.3 An affirmative post-qualification determination will be a pre-requisite for award of the contract to the lowest evaluated Bidder. A negative determination will result in rejection of the Bidder's bid, in which event the Purchaser will proceed to the next-lowest evaluated Bidder to make a similar determination of that Bidder's capabilities to perform satisfactorily.

33. Award Criteria

33.1 Pursuant to ITB Clauses 30, 31 and 36, the Purchaser will award the Contract to the Bidder whose bid has been determined to be substantially responsive and has been determined to be the lowest evaluated bid, provided further that the Bidder is determined to be qualified to perform the Contract satisfactorily, pursuant to ITB Clause 32.

34. Purchaser's Right to Accept Any Bid and to Reject Any or All Bids

34.1 The Purchaser reserves the right to accept or reject any bid, or to annul the bidding process and reject all bids at any time prior to contract award, without thereby incurring any liability to the affected Bidder or Bidders.

35. Purchaser's Right to Vary Quantities at Time of Award

35.1 The Purchaser reserves the right at the time of Contract award to increase or decrease, by the percentage indicated in the Bid Data Sheet, the quantity of contraceptives beyond that originally specified in the Schedule of Requirements without any change in unit price or other terms and conditions.

36. Notification of Award

36.1 Prior to the expiration of the period of bid validity, the Purchaser will notify the successful Bidder in writing by registered letter or by cable, to be subsequently confirmed in writing by registered letter, that its bid has been accepted.

36.2 The notification of award will constitute the formation of the Contract.

36.3 Upon the successful Bidder's furnishing of the signed Contract Form and performance security pursuant to ITB Clause 38, the Purchaser will promptly notify each unsuccessful Bidder and will discharge its bid security, pursuant to ITB Clause 17.

36.4 If, after notification of award, a Bidder wishes to ascertain the grounds on which its bid was not selected, it should address its request to the Purchaser. The Purchaser will promptly respond in writing to the unsuccessful Bidder.

36.5 The Purchaser shall publish in UNDB online and in the international advertisement websites the results identifying the bid and lot numbers and the following information: (i) name of each Bidder who submitted a Bid; (ii) bid prices as read out at bid opening; (iii) name and evaluated prices of each Bid that was evaluated; (iv) name of bidders whose bids were rejected and the reasons for their rejection; and (v) name of the winning Bidder, and the price it offered, as well as the duration and summary scope of the contract awarded. After publication of the award, unsuccessful bidders may request in writing to the Purchaser for a debriefing seeking explanations on the grounds on which their bids were not selected. The Purchaser shall promptly respond in writing to any unsuccessful Bidder who, after Publication of contract award, requests a debriefing.

37. Signing of Contract

37.1 Promptly after the Purchaser notifies the successful Bidder that its bid has been accepted, the Purchaser will send the Bidder the Contract Form provided in the Bidding Documents, incorporating all agreements between the parties.

37.2 Within twentyeight (28) days of receipt of the Contract Form, the successful Bidder shall sign and date the Contract Form and return it to the Purchaser.

38. Performance Security

38.1 Within twentyeight (28) days of the receipt of notification of award from the Purchaser, the successful Bidder shall furnish the performance security in accordance with the Conditions of Contract, using the Performance Security

Form provided in the Bidding Documents, or in another form acceptable to the Purchaser.

38.2 Failure of the successful Bidder to comply with the requirement of ITB Clause 37 or ITB Sub-Clause 38.1 shall constitute sufficient grounds for the annulment of the award and forfeiture of the bid security, in which event the Purchaser may make the award to the next-lowest evaluated bid submitted by a qualified Bidder or call for new bids.

Notes on the Bid Data Sheet Form

The Bid Data Sheet is intended to assist the Purchaser in providing the specific information in relation to corresponding clauses in the Instructions to Bidders included in Section I and has to be prepared for each specific procurement.

The Purchaser should specify in the Bid Data Sheet information and requirements specific to the circumstances of the Purchaser, the processing of the procurement, the applicable rules regarding bid price and currency and the bid evaluation criteria that will apply to the bids. In preparing Section II, the following aspects should be checked:

(a) The correct version of the Bid Data Sheet must be used as a base, dependent upon the type of contraceptives being procured. For example, if changes or additions are made to the Bid Data Sheet it may require changes to the corresponding SCC.

(b) Information that specifies and complements provisions of Section I, ITB, must be incorporated.

(c) Amendments and/or supplements, if any, to provisions of Section I, ITB, as required by the circumstances of the specific procurement, must also be incorporated.

Bid Data Sheet

The following specific data for the contraceptives to be procured shall complement, supplement or amend the provisions in the Instructions to Bidders (ITB). Whenever there is a conflict, the provisions in the Bid Data Sheet (BDS) shall prevail over those in the ITB.

A. General

ITB 1.1
Name of Purchaser: *[insert: name of Purchaser].*
Name of authorized Purchasing Agent: *[if appropriate, insert: name of the Purchasing Agent, otherwise state: "none"].*

Type of contraceptives: *[insert pharmaceuticals (including nutritional supplements and oral or injectable hormonal contraceptive), vaccines or condoms].*

Name and identification number of the Contract: *[insert: name and identification number of the Contract].*

ITB 4.1 (c)
Documentation requirements for eligibility of contraceptives. In addition to the documents stated in Clause 6.2 and 6.3 (a) and (b), the following documents should be included with the Bid:

[Insert: any other eligibility documentation required]

ITB 4.2
The Purchaser's country *[Insert: does or does not]* require registration of contraceptives.

[Note: If the Purchaser's country does not require registration of the contraceptives, delete 4.2 (b) and 4.2.1 below and insert the following language:

ITB Sub-Clause 4.2 is inapplicable. The Applicable Law does not require registration of the contraceptives to be supplied under the Contract.]

ITB 4.2 (b)
By the time of Contract signing, the successful Bidder shall have complied with the following documentary requirements in order to register the contraceptives to be supplied under the Contract: *[insert: specific documentary requirements or any other country specific requirement].*

Note: Because of the potential for delay when various government agencies must intervene in the registration process, bidders are alerted to inquire about registration requirements and procedures as early as possible.

ITB 4.2.1
For the purpose of obtaining additional information about the requirements for registration, Bidders may contact *[insert: name of agency, contact person, phone/fax/email address]*.

ITB 5.1 (a)
Qualification requirements for Bidders are:

[insert, as appropriate: quantifiable qualification criteria for experience and / or financial viability].

The following documents must be included with the bid:

Documentary evidence of the Bidder's qualifications to perform the Contract if its bid is accepted:

(i) that, in the case of a Bidder offering to supply contraceptives under the Contract, that the Bidder manufactures or otherwise produces (using ingredients supplied by primary manufacturers), evidence that the Bidder:
   (a) is incorporated in the country of manufacture of the contraceptives;
   (b) has been licensed by the regulatory authority in the country of manufacture to supply the contraceptives;
   (c) has manufactured and marketed the specific contraceptives covered by this Bidding Document for at least two (2) years, and for similar contraceptives for at least five (5) years;
   (d) has received a satisfactory GMP inspection certificate in line with the WHO certification scheme on pharmaceuticals moving in International Commerce from the regulatory authority (RA) in the country of manufacture of the contraceptives or has been certified by the competent authority of a member country of the Pharmaceuticals Inspection Convention (PIC), and has demonstrated compliance with the quality standards during the past two years prior to bid submission;

(ii) that, in the case of a Bidder offering to supply contraceptives under the Contract, the Bidder does not manufacture or otherwise produce:
   (a) that the Bidder has been duly authorized by a manufacturer of the contraceptives that meets the criteria under (i) above to supply the contraceptives in the Purchaser's country; and

The Bidder shall also submit the following additional information:

(a) a statement of installed manufacturing capacity;
(b) copies of its audited financial statements for the past three fiscal years;
(c) details of on-site quality control laboratory facilities and services and range of tests conducted;
(d) list of major supply contracts conducted within the last five years.

B. The Bidding Documents

ITB 9.1

Purchaser's / duly authorized Purchasing Agent's address: *[insert: Purchaser's address, telephone, telex, and facsimile numbers; also specify a responsible contact person or officer to whom Bidder communications should be addressed].*

C. Preparation of Bids

ITB 11.1

The language of the bid is: *[Insert "English" or " Spanish" or "French"].*

[In countries that the Bank has agreed with the Borrower that in addition to one internationally used language, bids may be also issued in the language of the Borrower's country (or the language used nationwide in the Borrower's country for commercial transactions), the following text shall be added:

"In addition to the above indicated language, these Bidding Documents have been issued in [insert the language of the Borrower's country or the language used nation-wide in the Borrower's Country for commercial transactions].

Bidders are permitted, at their choice, to submit their bids in one of the two languages above indicated. Bidders shall not submit bids in more than one language. The Contract to be signed with the winning Bidder shall be written in the language in which the Bid was submitted, which will be the language that shall govern the contractual relations between the Purchaser and the winning Bidder. A Bidder shall not sign a translated version of its Contract"].

ITB 12.1 (i) In addition to the documents stated in Paragraphs 12.1 (a) through (h), the following documents must be included with the Bid *[insert: list of documents]:*

[Sample clause]

Bidders who are not primary manufacturers should provide evidence that their product conforms to the quality standards of the primary manufacturer and they have the capacity to supply the specified quantities. A "primary manufacturer" is defined as a company that performs all the manufacturing and formulating operations needed to produce pharmaceuticals or nutritional supplements in their appropriate dosage forms, including processing, blending, formulating, filling, packing, labelling and quality testing. The Bidder shall furnish a certificate from the competent Regulatory Authority (RA) that the manufacturer is licensed to manufacture the contraceptives offered.

ITB 14.2 (b) (i) and (c) (iii)

Place of Destination: *[insert name of destination as per Incoterm used]*

ITB 14.2 (a) (iii);(b)(ii) and (c)(v)
"Final destination/site": *[insert name of location where the contraceptives are to be actually used]*

ITB 14.2 (b) (iii)
In addition to the CIP price specified in ITB 14.2 (b)(i), the price of the contraceptives manufactured outside the Purchaser's Country shall be quoted: *[insert appropriate Incoterm, other than CIP]*

ITB 14.5
Prices quoted by the Bidder shall be [state: "fixed"; or, if a price adjustment mechanism is required, then specify the exact formula that will apply, including the nature of the indices that will be used].

ITB 14.6
Bids are being invited for *[indicate "one or more items," or "individual contracts (lots)"]*

ITB 15.1 (b)
The currency to be used for quoting prices of the contraceptives and Services components of the contraceptives offered from within the Purchaser's country, as well as local currency expenditures for local technical support, training, maintenance, transportation, insurance, and other local costs incidental to delivery, is: *[select: currency of Purchaser's country / other currency, as specified by the Purchaser]*.

Note: Bid prices are usually lower if Bidders are allowed to quote and be paid in either the currency of expenditure or another internationally traded currency of their choice.

Normally the currency of bid and payment for locally supplied contraceptives is the currency of the Purchaser's country. However, Borrowers may allow domestic Bidders to bid in a stable foreign currency for their local costs. Alternatively, they may allow those prices to be adjusted. If payments must be made in the local currency to conform to local law or regulation, any such payments due to a domestic Supplier are converted from the currency of bid to local currency at the exchange rate prevailing at the time of payment.

The presence of such restriction on the currency of payment for locally supplied contraceptives, as well as the precise method of selecting the exchange rate to use in such a case (i.e., the date/time and source of the exchange rate), must be specified in the SCC regarding payment, along with the presence of such restrictions on the currency of payment for locally supplied contraceptives.

ITB 16.1
The bid validity period shall be *[insert: number (X)]* days after the deadline for bid submission, as specified below in reference to ITB Clause 21. Accordingly, each bid shall be valid through *[insert: the actual date of the expiration of the bid validity period (i.e., X days after the date of bid opening)]*.

Note: The bid validity period should be sufficient to permit completion of the evaluation, review of the recommended award by the management of the implementing agency and the Bank, the receipt of all necessary approvals, including the Bank's no objection and issuance of the notification of award. In most cases, ninety (90) days should be adequate, but whatever period is selected, it should be realistic so that requests for extensions are kept to the minimum.

Bid security must be valid twentyeight (28) days after the end of the bid validity period. Accordingly, a bid with a bid security that expires before *[insert: the actual **d**ate of the expiration of the bid security, i.e., twentyeight (28) days after the end of the bid validity period]* shall be rejected as nonresponsive.

Note: Bank experience also shows that many bids are rejected on the basis of simple errors in calculating the bid security validity period. Accordingly, the Purchaser should explicitly state above the date through which bid security must be valid.

ITB 17.1
[insert one of the following options:

No Bid Security is required; or

Bid shall include a Bid Security (issued by bank or surety) included in Section VIII Sample Forms; or

(c) Bid shall include "Bid Securing Declaration" using the form included in Section VIII Sample Forms.]

The amount of bid security required is: *[insert: fixed amount and currency]*.

Note: The amount may be expressed as either a fixed amount or an amount "not less than" a specified percentage of the Bidder's bid price. To avoid premature disclosure of bid prices by commercial bank personnel or others, a fixed amount of not less than 2 percent to no more than 3 percent of the budget estimate for the contract (estimated) bid amount is strongly recommended. (Requiring higher bid security risks driving away potentially qualified Bidders.) Asking for smaller, or even no bid security at all, however, is acceptable for simple contracts where the market is relatively stable and mature.

Also, in the case of Bidding Documents covering multiple lots, a bid security should be specified as representing not less than "x" percent of the total Bid Price for all lots covered by the bid.

ITB 17.8
If the Bidder incurs any of the actions prescribed in subparagraphs (a) or (b) of this provision, the Borrower will declare the Bidder ineligible to be awarded contracts by the Employer for a period of _____ years.

ITB 18.1
Alternative bids *[indicate: will or will not]* be accepted.

Note: When Bidders are permitted to submit alternative bids, only the alternative submitted by the Bidder whose basic bid is the lowest evaluated bid will be considered. Such alternatives will be evaluated in accordance with the evaluation criteria and methods specified in this BDS. An alternative bid can be selected for award only if it was submitted by the Bidder whose basic bid is the lowest evaluated bid. The alternative bid must be fully responsive to the requirements specified in the Bid Data Sheet, the SCC and the Specifications of the Bidding Documents and the lowest evaluated bid when compared with the basic bid submitted by the bidder.

The evaluation criteria are *[insert: criteria]*.

Requirements for responsive bids are *[insert: requirements]*.

ITB 19.1
Required number of copies of the bid: *[insert: number (X) of copies]*.

D. Submission of Bids

ITB 20.1
Bidders *[insert "shall" or "shall not"]* have the option of submitting their bids electronically.

If bidders shall have the option of submitting their bids electronically, the electronic bidding submission procedures shall be: *[insert a description of the electronic bidding submission procedures]*

ITB 20.2 (b)
The address for bid submission is: *[insert: address adequate for mail, courier, or physical delivery, including responsible officer or person]*.

Note: Do not use a postal box or similar address.

ITB 20.2 (c) & (d)
See the above data for ITB 1.1 for the name of the Contract.

The Invitation for Bids title and number are: *[if applicable, insert: Invitation for Bids Title and Invitation for Bids Number (if any); otherwise, state "none"]*.

See the below data for ITB 21.1 for the deadline for bid submission.

Note: The Purchaser should establish a clear and recognizable numbering system for its Contracts. Failure to do so typically results in misunderstandings in routine communications, review delays and inadequate monitoring of overall project progress.

ITB 21.1
See the above data for ITB Sub-Clause 20.2 (b) for the address and deadline for bid submission.

Deadline for bid submission is: *[insert: date and time].*

Note: The bid submission date is generally six to twelve weeks from the date of issuance of the Bidding Documents, depending on the value, scope and/or complexity of the contraceptives being purchased.

ITB 22.1
See the above data for ITB Sub-Clause 21.1 for the deadline for bid submission.

ITB 25.2 (a)
The required number of copies of bid modifications is the same as the number of copies of the original bid specified above in the data for ITB Sub-Clause 19.1.

ITB 23.3 (a)
See the above data for ITB Paragraph 20.2 (b) for the address to use for submission of a bid withdrawal notice.

E. Bid Opening and Evaluation

ITB 24.1
Time, date and place for bid opening are: *[insert: time, date, and place].*

If electronic bid submission is permitted in accordance with ITB sub-clause 20.1, the specific bid opening procedures shall be: *[insert description of the procedures]*

Note: The date for the bid opening should be the same as specified for the bid submission deadline, and the time should be shortly thereafter, to minimize possible complaints regarding insecure storage arrangements. If the address for bid submission and the place of bid opening are not the same, adequate time between bid submission deadline and bid opening times should be allowed to accommodate physically moving the bids from one site to the other. However, this delay must be kept to a minimum and reflect only the requirements of logistics, say, no more than two hours.

ITB 29.3
The currency chosen for the purpose of converting to a common currency is: *[specify either: the local currency, or a convertible currency commonly used for procurement of contraceptives, for example, U.S. dollars].*

The source of exchange rate is: *[insert: publication, name of bank, etc.].*

Note: If the common currency is other than the local currency, for example, U.S. dollars, indicate the name of an internationally circulated newspaper that lists daily currency selling exchange rates which will be used for converting prices in foreign currencies. For prices

in local currency, and if the common currency selected above is the local currency, specify either the Central Bank or a commercial bank in the Purchaser's country, and identify the publication where the specified rates are published.

The date of exchange rate determination is: *[select: **a** date that shall not be earlier than four (4) weeks prior to the original deadline for the receipt of bids as specified for ITB Sub-Clause 23.1, and no later than the expiration of the original bid validity period].*

ITB 30.4 (d)
The evaluation will take into account [insert: factors and other specific criteria].

ITB 30.5
The factors retained pursuant to ITB Sub-Clause 30.4 and the quantification methods are: *[insert: factors].*

ITB 30.5 (b) (i) (ii) & (iii)
Delivery schedule *[specify: relevant parameters in accordance with option selected].*

The adjustment per week for delivery delays beyond the time specified in the Schedule of Requirements is *[specify: adjustment in percentage].*

Or

The adjustment per week for delivery delays beyond the range of weeks specified in the Schedule of Requirements is *[specify: adjustment in percentage].*

Or

The adjustment for partial shipments is *[specify: adjustments for early and late deliveries].*

Note: For evaluation purposes, a rate of one-half (0.5) percent per week is a reasonable figure.

ITB 30.5 (c) (ii)
The Purchaser *[select: will / will not]* accept deviations in the payment schedule in the SCC.

Note: If deviations are accepted, add the following text.

The percentage adjustment for payment schedule deviations is:
[insert: percentage] % per week.

Note: If inflation expectations widely diverge between local and foreign currencies, and Bidders are expected to quote significant amounts in local currencies, different adjustment rates for local and foreign currency prices should be provided.

ITB 30.5 (d) *[insert: other factors to be used in the evaluation and their evaluation method or reference to the Technical Specifications]*
Evaluation criteria for items/lots

[Select one of the two sample clauses below]

If bids have been invited for items only, the BDS should state the following:

Bidders may bid for any one or more items. Bids will be evaluated for each item and the Contract will comprise the item(s) awarded to the successful Bidder.

If lots will be accepted, the BDS should state the following:

Bidders can bid for one or more lots. Bids will be evaluated lot by lot. Bidders must quote for the entire quantity of each item and at least eighty percent (80%) of the number of items in the lot to be treated as substantially responsive.

Bid evaluation of such bids will be carried out as per the following procedures. The average price of an item quoted by substantially responsive bidders will be added to the bid price of those who did not quote for that item and the equivalent total cost of the bid so determined will be used for bid comparison, evaluation, and award.

ITB 31.1
A margin of domestic preference *[specify: will or will not]* apply.

F. Post-qualification and Award of Contract

ITB 32.1
Post-qualification
[insert: Any specific post-qualification requirements, such as the required number of years of manufacturing experience.]

ITB 35.1 Percentage for increase or decrease of quantity of contraceptives originally specified: *[insert: percentage not more than 20%].*

Bid Data Sheet

Pharmaceuticals

(Additional Clauses)

[Note: The below data should be included in the Bid Data Sheet used in Bidding Documents for the procurement of pharmaceuticals.]

ITB 4.3 (c)
[Sample clauses]

The contraceptives offered should meet the specified pharmacopoeial standards as stated in the Technical Specification. If the contraceptives offered are not included in one of the specified pharmacopoeias (e.g., the case of a new drug), the Bidder will provide testing protocols and alternative reference standards.

ITB 5.1 (a) & (d)
Documentary evidence of the Bidder's qualifications to perform the Contract if its bid is accepted:

(ii)

(d) has a Good Distribution Practice (GDP) Certificate where appropriate.

The Bidder will submit the following additional information:

(e) list of pharmaceuticals being manufactured by the Bidder with product registration/license number and date.

(f) a Certificate of Pharmaceutical Product as recommended by the WHO for each item offered.

Notes on the General Conditions of Contract

The General Conditions of Contract (GCC), read in conjunction with the Special Conditions of Contract (SCC) and other documents listed in the Contract Agreement, should be a complete document expressing all the rights and obligations of the parties.

GCC must remain unaltered. Contract-specific information, deletions, extensions and modifications to the GCC shall be introduced only through the SCC.

General Conditions of Contract

1. Definitions

1.1 In this Contract, the following terms shall be interpreted as indicated:

(a) "The Contract" means the agreement entered into between the Purchaser and the Supplier, as recorded in the Contract Form signed by the parties, including all attachments and appendices thereto and all documents incorporated by reference therein.

(b) "The Contract Price" means the price payable to the Supplier under the Contract for the full and proper performance of its contractual obligations.

(c) "Day" means calendar day.

(d) "Effective Date" means the date on which this Contract becomes effective pursuant to GCC Clause 6.2.

(e) "End User" means the organization(s) where the contraceptives will be used, as named in the SCC.

(f) "GCC" means the General Conditions of Contract contained in this section.

(g) "The contraceptives" means all oral and injectable forms of contraception as well as IUD's and condoms that the Supplier is required to supply to the Purchaser under the Contract.

(h) "The Purchaser" means the organization purchasing the contraceptives, as named in the SCC.

(i) "The Purchaser's country" is the country named in the SCC.

(j) "Registration Certificate" means the certificate of registration or other documents in lieu thereof establishing that the contraceptives supplied under the Contract are registered for use in the Purchaser's country in accordance with the Applicable Law.

(k) "SCC" means the Special Conditions of Contract.

(l) "The Services" means those services ancillary to the supply of the contraceptives, such as transportation and insurance, and any other incidental services, such as provision of technical assistance, training and other such obligations of the Supplier covered under the Contract.

(m) "The Site," where applicable, means the place or places named in the SCC.

(n) "The Supplier" means the individual or firm supplying the contraceptives under this Contract, as named in the SCC.

2. Application

2.1 These General Conditions shall apply to the extent that they are not superseded by provisions of other parts of the Contract.

3. Standards

   3.1 The contraceptives supplied under this Contract shall conform to the standards mentioned in the Technical Specifications and, when no applicable standard is mentioned, to the authoritative standards appropriate to the contraceptives' country of origin. Such standards shall be the latest issued by the concerned institution.

4. Use of Contract Documents and Information; Inspection and Audit by the Purchaser

   4.1 The Supplier shall not, without the Purchaser's prior written consent, disclose the Contract, or any provision thereof, or any specification, plan, drawing, pattern, sample or information furnished by or on behalf of the Purchaser in connection therewith, to any person other than a person employed by the Supplier in the performance of the Contract. Disclosure to any such employed person shall be made in confidence and shall extend only so far as may be necessary for purposes of such performance.

   4.2 The Supplier shall not, without the Purchaser's prior written consent, make use of any document or information enumerated in GCC Sub-Clause 4.1 except for purposes of performing the Contract.

   4.3 Any document, other than the Contract itself, enumerated in GCC Sub-Clause 4.1 shall remain the property of the Purchaser and shall be returned (all copies) to the Purchaser on completion of the Supplier's performance under the Contract if so required by the Purchaser.

   4.4 The Supplier shall permit the Purchaser and/or persons appointed by the Purchaser to inspect the Supplier's offices and/or the accounts and records of the Supplier and its sub-contractors relating to the performance of the Contract. The Supplier's attention is drawn to Clause 22 which provides, inter alia, that acts intended to materially impede the exercise of the Purchaser's inspection and audit rights provided for under this Sub-Clause constitute a prohibited practice subject to contract termination.

5. Certification of contraceptives in Accordance with Laws of the Purchaser's Country

   5.1 If required under the Applicable Law, contraceptives supplied under the Contract shall be registered for use in the Purchaser's country. The Purchaser undertakes to cooperate with the Supplier to facilitate registration of the contraceptives for use in the Purchaser's country.

   5.2 Unless otherwise specified in the SCC, the Contract shall become effective on the date ("the Effective Date") that the Supplier receives written notification from the relevant authority in the Purchaser's country that the contraceptives have been registered for use in the Purchaser's country.

   5.3 If thirty (30) days, or such longer period specified in the SCC, elapse from the date of Contract signing and the Contract has not become effective pursuant to Sub-Clause 5.2 above, then either party may, by not less than seven (7) days' written

notice to the other party, declare this Contract null and void. In such event, the Supplier's performance security shall be promptly returned.

6. Patent Rights

6.1 The Supplier shall indemnify the Purchaser against all third party claims of infringement of patent, trademark or industrial design rights arising from use of the contraceptives or any part thereof in the Purchaser's country.

7. Performance Security

7.1 Within twentyeight (28) days of receipt of the notification of Contract award, the successful Bidder shall furnish to the Purchaser the performance security in the amount specified in the SCC.

7.2 The proceeds of the performance security shall be payable to the Purchaser as compensation for any loss resulting from the Supplier's failure to complete its obligations under the Contract.

7.3 The performance security shall be denominated in the currency of the Contract, or in a freely convertible currency acceptable to the Purchaser, and shall be in one of the following forms:

(a) a bank guarantee or an irrevocable letter of credit issued by a reputable bank located in the Purchaser's country or abroad, acceptable to the Purchaser, in the format provided in the Bidding Documents or another format acceptable to the Purchaser; or

(b) a cashier's or certified check.

7.4 The performance security will be discharged by the Purchaser and returned to the Supplier not later than thirty (30) days following the date of completion of the Supplier's performance obligations under the Contract, including any warranty obligations, unless specified otherwise in the SCC.

8. Inspections and Tests

8.1 The Purchaser or its representative shall have the right to inspect and/or to test the contraceptives to confirm their conformity to the Contract specifications. The SCC and the Technical Specifications shall specify what inspections and tests the Purchaser requires and where they are to be conducted. The Purchaser shall notify the Supplier in writing, in a timely manner, of the identity of any representatives retained for these purposes.

(a) Said inspection and testing is for the Purchaser's account. In the event that inspection and testing is required prior to dispatch, the contraceptives shall not be shipped unless a satisfactory inspection and quality control report has been issued in respect of those contraceptives.

(b) The Supplier may have an independent quality test conducted on a batch ready for shipment. The cost of such tests will be borne by the Supplier.

(c) Upon receipt of the contraceptives at place of final destination, the Purchaser's representative shall inspect the contraceptives or part of the contraceptives to ensure that they conform to the condition of the Contract and advise the Purchaser that the contraceptives were received in apparent good order. The Purchaser will issue an Acceptance Certificate to the Supplier in respect of such contraceptives (or part of contraceptives). The Acceptance Certificate shall be issued within ten (10) days of receipt of the contraceptives or part of contraceptives at place of final destination.

8.2 Where the Supplier contests the validity of the rejection by the Purchaser or his representative, of any inspection as required by 8.1 above conducted before shipment or at ultimate destination, whether based on product or packing grounds, a sample, drawn jointly by the Supplier and Purchaser or his or her representative and authenticated by both, will be forwarded for umpire analysis within four weeks of the time the Supplier contests to an independent agency mutually agreed by the Purchaser and Supplier. The umpire's finding, which will be promptly obtained, will be final and binding on both parties. The cost of umpire analysis will be borne by the losing party.

9. Packing

9.1 The Supplier shall provide such packing of the contraceptives as is required to prevent their damage or deterioration during transit to their final destination, as indicated in the Contract. The packing shall be sufficient to withstand, without limitation, rough handling during transit and exposure to extreme temperatures, salt and precipitation during transit and open storage. Packing case size and weights shall take into consideration, where appropriate, the remoteness of the contraceptives' final destination and the absence of heavy handling facilities at all points in transit.

9.2 The packing, marking and documentation within and outside the packages shall comply strictly with such special requirements as shall be expressly provided for in the Contract, including additional requirements, if any, specified in the SCC or Technical Specifications, and in any subsequent instructions ordered by the Purchaser.

10. Delivery and Documents

10.1 Delivery of the contraceptives shall be made by the Supplier in accordance with the terms specified in the Schedule of Requirements. The details of shipping and/or other documents to be furnished by the Supplier are specified in the SCC.

10.2 For purposes of the Contract, "EXW," "FOB," "FCA," "CIF," "CIP," and other trade terms used to describe the obligations of the parties shall have the meanings assigned to them by the current edition of Incoterms published by the International Chamber of Commerce, Paris.

10.3 Documents to be submitted by the Supplier are specified in the SCC. INCOTERMS provides a set of international rules for the interpretation of the more commonly used trade terms.

11. Insurance

11.1 The contraceptives supplied under the Contract shall be fully insured in a freely convertible currency against loss or damage incidental to manufacture or acquisition, transportation, storage and delivery in the manner specified in the SCC.

11.2 Where delivery of the contraceptives is required by the Purchaser on a CIF or CIP basis, the Supplier shall arrange and pay for cargo insurance, naming the Purchaser as beneficiary. Where delivery is on an FOB or FCA basis, insurance shall be the responsibility of the Purchaser.

12. Transportation

12.1 Where the Supplier is required under Contract to deliver the contraceptives FOB, transport of the contraceptives, up to and including the point of putting the contraceptives on board the vessel at the specified port of loading, shall be arranged and paid for by the Supplier, and the cost thereof shall be included in the Contract Price. Where the Supplier is required under the Contract to deliver the contraceptives FCA, transport of the contraceptives and delivery into the custody of the carrier at the place named by the Purchaser or other agreed point shall be arranged and paid for by the Supplier, and the cost thereof shall be included in the Contract Price.

12.2 Where the Supplier is required under Contract to deliver the contraceptives CIF or CIP, transport of the contraceptives to the port of destination or such other named place of destination in the Purchaser's country, as shall be specified in the Contract, shall be arranged and paid for by the Supplier, and the cost thereof shall be included in the Contract Price.

12.3 Where the Supplier is required under the Contact to transport the contraceptives to a specified place of destination within the Purchaser's country, defined as the Site, transport to such place of destination in the Purchaser's country, including insurance and storage, as shall be specified in the Contract, shall be arranged by the Supplier, and related costs shall be included in the Contract Price.

12.4 Where the Supplier is required under Contract to deliver the contraceptives CIF or CIP, no restriction shall be placed on the choice of carrier. Where the Supplier is required under Contract (a) to deliver the contraceptives FOB or FCA, and (b) to arrange on behalf and at the expense of the Purchaser for international transportation on specified carriers or on national flag carriers of the Purchaser's country, the Supplier may arrange for such transportation on alternative carriers if

the specified or national flag carriers are not available to transport the contraceptives within the period(s) specified in the Contract.

13. Incidental Services

13.1 The Supplier shall provide such incidental services, if any, as are specified in the SCC.

13.2 Prices charged by the Supplier for incidental services, if not included in the Contract Price for the contraceptives, shall be agreed upon in advance by the parties and shall not exceed the prevailing rates charged to other parties by the Supplier for similar services.

14. Warranty

14.1 All contraceptives must be of fresh manufacture and must bear the dates of manufacture and expiry.

The Supplier further warrants that all contraceptives supplied under the Contract will have remaining a minimum of five-sixths (5/6) of the specified shelf life upon delivery at port/airport of entry for contraceptives with a shelf life of more than two years and three-fourths (3/4) for contraceptives with a shelf life of two years or less, unless otherwise specified in the SCC; have "overages" within the ranges set forth in the Technical Specifications, where applicable; are not subject to recall by the applicable regulatory authority due to unacceptable quality or an adverse drug reaction; and in every other respect will fully comply in all respects with the Technical Specifications and with the conditions laid down in the Contract.

14.2 The Purchaser shall have the right to make claims under the above warranty for three months after the contraceptives have been delivered to the final destination indicated in the Contract. Upon receipt of a written notice from the Purchaser, the Supplier shall, with all reasonable speed, replace the defective contraceptives without cost to the Purchaser. The Supplier will be entitled to remove, at his own risk and cost, the defective contraceptives once the replacement contraceptives have been delivered.

14.3 In the event of a dispute by the Supplier, a counteranalysis will be carried out on the manufacturer's retained samples by an independent neutral laboratory agreed by both the Purchaser and the Supplier. If the counteranalysis confirms the defect, the cost of such analysis will be borne by the Supplier as well as the replacement and disposal of the defective contraceptives. In the event of the independent analysis confirming the quality of the product, the Purchaser will meet all costs for such analysis.

14.4 If, after being notified that the defect has been confirmed pursuant to GCC Sub-Clause 14.2 above, the Supplier fails to replace the defective contraceptives within the period specified in the SCC, the Purchaser may proceed to take such

remedial action as may be necessary, including removal and disposal, at the Supplier's risk and expense and without prejudice to any other rights that the Purchaser may have against the Supplier under the Contract. The Purchaser will also be entitled to claim for storage in respect of the defective contraceptives for the period following notification and deduct the sum from payments due to the Supplier under this Contract.

14.5 Recalls. In the event any of the contraceptives are recalled, the Supplier shall notify the Purchaser within fourteen (14) days, providing full details of the reason for the recall and promptly replace, at its own cost, the items covered by the recall with contraceptives that fully meet the requirements of the Technical Specification and arrange for collection or destruction of any defective contraceptives. If the Supplier fails to fulfill its recall obligation promptly, the Purchaser will, at the Supplier's expense, carry out the recall.

15. Payment

15.1 The method and conditions of payment to be made to the Supplier under this Contract shall be specified in the SCC.

15.2 The Supplier's request(s) for payment shall be made to the Purchaser in writing, accompanied by an invoice describing, as appropriate, the contraceptives delivered and Services performed, and by documents submitted pursuant to GCC Clause 10, and upon fulfillment of other obligations stipulated in the Contract.

15.3 Payments shall be made promptly by the Purchaser, but in no case later than sixty (60) days after submission of an invoice or claim by the Supplier.

15.4 The currency or currencies in which payment is made to the Supplier under this Contract shall be specified in the SCC subject to the following general principle: Payment will be made in the currency or currencies in which the payment has been requested in the Supplier's bid.

15.5 All payments shall be made in the currency or currencies specified in the SCC pursuant to GCC 15.4.

16. Prices

16.1 Prices charged by the Supplier for contraceptives delivered and Services performed under the Contract shall not vary from the prices quoted by the Supplier in its bid, with the exception of any price adjustments authorized in the SCC or in the Purchaser's request for bid validity extension, as the case may be.

17. Change Orders

17.1 The Purchaser may at any time, by a written order given to the Supplier pursuant to GCC Clause 30, make changes within the general scope of the Contract in any one or more of the following:

(a) specifications, where contraceptives to be furnished under the Contract are to be specifically manufactured for the Purchaser;

(b) the method of shipment or packing;

(c) the place of delivery; and/or

(d) the Services to be provided by the Supplier.

17.2 If any such change causes an increase or decrease in the cost of, or the time required for, the Supplier's performance of any provisions under the Contract, an equitable adjustment shall be made in the Contract Price or delivery schedule, or both, and the Contract shall accordingly be amended. Any claims by the Supplier for adjustment under this clause must be asserted within thirty (30) days from the date of the Supplier's receipt of the Purchaser's change order.

18. Contract Amendments

18.1 Subject to GCC Clause 17, no variation in or modification of the terms of the Contract shall be made except by written amendment signed by the parties.

19. Assignment

19.1 The Supplier shall not assign, in whole or in part, its obligations to perform under this Contract, except with the Purchaser's prior written consent.

20. Delays in the Supplier's Performance

20.1 Delivery of the contraceptives and performance of Services shall be made by the Supplier in accordance with the time schedule prescribed by the Purchaser in the Schedule of Requirements.

20.2 If at any time during performance of the Contract, the Supplier or its subcontractor(s) should encounter conditions impeding timely delivery of the contraceptives and performance of Services, the Supplier shall promptly notify the Purchaser in writing of the fact of the delay, its likely duration and its cause(s). As soon as practicable after receipt of the Supplier's notice, the Purchaser shall evaluate the situation and may at its discretion extend the Supplier's time for performance, with or without liquidated damages, in which case the extension shall be ratified by the parties by amendment of Contract.

20.3 Except as provided under GCC Clause 23, a delay by the Supplier in the performance of its delivery obligations shall render the Supplier liable to the imposition of liquidated damages pursuant to GCC Clause 21, unless an extension of time is agreed upon pursuant to GCC Clause 20.2 without the application of liquidated damages.

21. Liquidated Damages

21.1 Subject to GCC Clause 23, if the Supplier fails to deliver any or all of the contraceptives or to perform the Services within the period(s) specified in the

Contract, the Purchaser shall, without prejudice to its other remedies under the Contract, deduct from the Contract Price, as liquidated damages, a sum equivalent to the percentage specified in the SCC of the delivered price of the delayed contraceptives or unperformed Services for each week or part thereof of delay until actual delivery or performance, up to a maximum deduction of the percentage specified in the SCC. Once the maximum is reached, the Purchaser may consider termination of the Contract pursuant to GCC Clause 22.

22. Termination for Default

22.1 The Purchaser, without prejudice to any other remedy for breach of Contract, by written notice of default sent to the Supplier, may terminate this Contract in whole or in part:

(a) if the Supplier fails to deliver any or all of the contraceptives within the period(s) specified in the Contract, or within any extension thereof granted by the Purchaser pursuant to GCC Clause 20; or

(b) if the contraceptives do not meet the Technical Specifications stated in the Contract; or

(c) if the Supplier fails to provide any registration or other certificates in respect of the contraceptives within the time specified in the Special Conditions.

(d) if the Purchaser determines that the Supplier has engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for or in executing the Contract, then the Purchaser may, after giving 14 days notice to the Supplier, terminate the Supplier's employment under the Contract and cancel the contract, and the provisions of Clause 22 shall apply as if such expulsion had been made under Sub-Clause 22.1.

For the purposes of this Sub-Clause:

(i) "corrupt practice" is the offering, giving, receiving or soliciting, directly or indirectly, of anything of value to influence improperly the actions of another party;

(ii) "fraudulent practice" is any act or omission, including a misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain a financial or other benefit or to avoid an obligation;

(iii)"collusive practice" is an arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another party;

(iv)"coercive practice" is impairing or harming, or threatening to impair or harm, directly or indirectly, any party or the property of the party to influence improperly the actions of a party;

(v) "obstructive practice" is

(aa) deliberately destroying, falsifying, altering or concealing of evidence material to the investigation or making false statements to investigators in order to materially impede a Bank investigation into allegations of a corrupt, fraudulent, coercive or collusive practice; and/or threatening, harassing or intimidating any party to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation; or

(bb) acts intended to materially impede the exercise of the Bank's inspection and audit rights provided for under Clause 5.

(e) should any employee of the Supplier be determined to have engaged in corrupt, fraudulent, collusive, coercive or obstructive practice during the purchase of the contraceptives, then that employee shall be removed.

(f) if the Supplier fails to perform any other obligation(s) under the Contract.

22.2 In the event the Purchaser terminates the Contract in whole or in part, pursuant to GCC Clause 22.1, the Purchaser may procure, upon such terms and in such manner as it deems appropriate, contraceptives or Services similar to those undelivered, and the Supplier shall be liable to the Purchaser for any excess costs for such similar contraceptives or Services. However, the Supplier shall continue performance of the Contract to the extent not terminated.

23. *Force Majeure*

23.1 Notwithstanding the provisions of GCC Clauses 20, 21, and 22, the Supplier shall not be liable for forfeiture of its performance security, liquidated damages or termination for default if and to the extent that its delay in performance or other failure to perform its obligations under the Contract is the result of an event of *force majeure*.

23.2 For purposes of this clause, "*force majeure*" means an event beyond the control of the Supplier and not involving the Supplier's fault or negligence and not foreseeable. Such events may include, but are not restricted to, acts of the Purchaser in its sovereign capacity, wars or revolutions, fires, floods, epidemics, quarantine restrictions and freight embargoes.

23.3 If a *force majeure* situation arises, the Supplier shall promptly notify the Purchaser in writing of such condition and the cause thereof. Unless otherwise directed by the Purchaser in writing, the Supplier shall continue to perform its obligations under the Contract as far as is reasonably practical and shall seek all reasonable alternative means for performance not prevented by the *force majeure* event.

24. Termination for Insolvency

24.1 The Purchaser may at any time terminate the Contract by giving written notice to the Supplier if the Supplier becomes bankrupt or otherwise insolvent. In this event, termination will be without compensation to the Supplier, provided that such termination will not prejudice or affect any right of action or remedy that has accrued or will accrue thereafter to the Purchaser.

25. Termination for Convenience

25.1 The Purchaser, by written notice sent to the Supplier, may terminate the Contract, in whole or in part, at any time for its convenience. The notice of termination shall specify that termination is for the Purchaser's convenience, the extent to which performance of the Supplier under the Contract is terminated and the date upon which such termination becomes effective.

25.2 The contraceptives that are complete and ready for shipment within thirty (30) days after the Supplier's receipt of notice of termination shall be accepted by the Purchaser at the Contract terms and prices. For the remaining contraceptives, the Purchaser may elect:

(a) to have any portion completed and delivered at the Contract terms and prices; and/or

(b) to cancel the remainder and pay to the Supplier an agreed amount for partially completed contraceptives and Services and for materials and parts previously procured by the Supplier.

26. Settlement of Disputes

26.1 If any dispute or difference of any kind whatsoever shall arise between the Purchaser and the Supplier in connection with or arising out of the Contract, the parties shall make every effort to resolve amicably such dispute or difference by mutual consultation.

26.2 If, after thirty (30) days, the parties have failed to resolve their dispute or difference by such mutual consultation, then either the Purchaser or the Supplier may give notice to the other party of its intention to commence arbitration, as hereinafter provided, as to the matter in dispute, and no arbitration in respect of this matter may be commenced unless such notice is given.

26.2.1 Any dispute or difference in respect of which a notice of intention to commence arbitration has been given in accordance with this Clause shall be finally settled by arbitration. Arbitration may be commenced prior to or after delivery of the contraceptives under the Contract.

26.2.2 Arbitration proceedings shall be conducted in accordance with the rules of procedure specified in the SCC.

26.3 Notwithstanding any reference to arbitration herein,

(a) the parties shall continue to perform their respective obligations under the Contract unless they otherwise agree; and

(b) the Purchaser shall pay the Supplier any monies due the Supplier.

27. Limitation of Liability

27.1 Except in cases of criminal negligence or willful misconduct, and in the case of infringement pursuant to Clause 7,

(a) the Supplier shall not be liable to the Purchaser, whether in contract, tort or otherwise, for any indirect or consequential loss or damage, loss of use, loss of production or loss of profits or interest costs, provided that this exclusion shall not apply to any obligation of the Supplier to pay liquidated damages to the Purchaser; and

(b) the aggregate liability of the Supplier to the Purchaser, whether under the Contract, in tort or otherwise, shall not exceed the total Contract Price, provided that this limitation shall not apply to the cost of repairing or replacing defective equipment.

28. Governing Language

28.1 The Contract shall be written in the language specified in the SCC. Subject to GCC Clause 30, the version of the Contract written in the specified language shall govern its interpretation. All correspondence and other documents pertaining to the Contract that are exchanged by the parties shall be written in the same language.

29. Applicable Law

29.1 The Contract shall be interpreted in accordance with the laws of the Purchaser's country, unless otherwise specified in the SCC.

30. Notices

30.1 Any notice given by one party to the other pursuant to this Contract shall be sent to the other party in writing or by cable, telex or facsimile and confirmed in writing to the other party's address specified in the SCC.

30.2 A notice shall be effective when delivered or on the notice's effective date, whichever is later.

31. Taxes and Duties

31.1 A Supplier supplying contraceptives from abroad shall be entirely responsible for all taxes, stamp, duties, license fees and other such levies imposed outside the Purchaser's country.

31.2 A Supplier supplying contraceptives offered locally shall be entirely responsible for all taxes, duties, license fees, etc., incurred until delivery of the contracted contraceptives to the Purchaser.

Notes on the Special Conditions of Contract

Similar to the Bid Data Sheet, the clauses in the Special Conditions of Contract are intended to assist the Purchaser in providing Contract-specific information in relation to corresponding clauses in the General Conditions of Contract (GCC).

The Special Conditions of Contract complement the GCC, specifying contractual requirements linked to the special circumstances of the Purchaser, the Purchaser's country, the sector and the contraceptives purchased. In preparing this section, the following aspects should be checked:

(a) Information that complements provisions of the GCC must be incorporated in the SCC.

(b) Amendments and/or supplements to provisions of the GCC, as necessitated by the circumstances of the specific purchase, must also be incorporated.

Note

The procuring unit cannot submit the contract for relevant authority signature until registration of the contraceptives has been completed. It is critically important for the Procurement Unit to be aware of registration status and to monitor progress of registration since Drugs Regulatory registration procedures can take time and delay contract signing which, in turn, can delay the delivery date of the contraceptives.

Special Conditions of Contract

The following Special Conditions of Contract shall supplement the General Conditions of Contract. Whenever there is a conflict, the provisions herein shall prevail over those in the General Conditions of Contract. The corresponding clause number of the GCC is indicated in parentheses.

[Instructions for completing the Special Conditions of Contract are provided as needed in the notes in italics mentioned for the relevant SCC. Where sample provisions are furnished, they are only illustrative of the provisions that the Purchaser should draft specifically for each procurement.]

GCC 1.1 (g)
The Purchaser is: [insert: name of Purchaser].

GCC 1.1 (h)
The Purchaser's country is: [insert: name of Purchaser's country].

GCC 1.1 (i)
The Supplier is: [insert: name of Supplier].

GCC 1.1 (k)
The Site is/are: [insert, if applicable: identity of Site, street address and city, or insert: "as specified in the Schedule of Requirements"].

GCC 1.1 (m)
The end user is: [insert, if applicable: the organization(s) stated in the Schedule of Requirements, where the contraceptives will be used].

GCC 5.1
The registration and other certification necessary to prove registration in Purchaser's country is [insert: details of registration and other certification necessary to prove registration in Purchaser's country.]

GCC 5.2
The Effective Date of the Contract is [insert: date of Contract signing if EITHER: (i) the contraceptives have already been registered at the time of Contracting signing OR (ii) registration of the contraceptives is not a requirement under the Applicable Law. Otherwise, delete and insert "NOT USED."]

GCC 5.3
The time period shall be [insert: a number greater than 30] days.

[If not used, delete and insert "NOT USED."]

GCC 7.1
Performance security shall be for an amount equal to [insert: number].

Note: Five (5) to ten (10) percent of the Contract Price is a reasonable amount.

GCC 7.4
Any additional requirements related to the discharge of performance security are [insert: any additional requirement related to the discharge of the performance security, or state: "There are no Special Conditions of Contract applicable to GCC Sub-Clause 7.4"].

GCC 8.1
[insert: any additional requirement related to the inspections and tests, or state: "There are no Special Conditions of Contract applicable to GCC Sub-Clause 8."]

GCC 9.2
[insert: Any necessary additional requirements with respect to packing and marking or state that additional requirements are indicated in the Technical Specifications.]

GCC 10.1 & 10.3
Sample provision (CIF/CIP terms)

For contraceptives supplied from abroad:

Upon shipment, the Supplier shall notify the Purchaser and the insurance company in writing the full details of the shipment, including Contract number, description of the contraceptives, quantity, date and place of shipment, mode of transportation and estimated date of arrival at place of destination. In the event of contraceptives sent by airfreight, the Supplier shall notify the Purchaser a minimum of fortyeight (48) hours ahead of dispatch, the name of the carrier, the flight number, the expected time of arrival and the waybill number. The Supplier shall fax and then send by courier the following documents to the Purchaser, with a copy to the insurance company:

(i) three originals and two copies of the Supplier's invoice, showing Purchaser as [enter correct description of Purchaser for customs purposes]; the Contract number, contraceptives description, quantity, unit price and total amount. Invoices must be signed in original, stamped, or sealed with the company stamp/seal;

(ii) one original and two copies of the negotiable, clean, on-board through bill of lading marked "freight prepaid" and showing Purchaser as [enter correct name of Purchaser for customs purposes] and Notify Party as stated in the Contract, with delivery through to final destination as per the Schedule of Requirements and two copies of non-negotiable bill of lading, or three copies of railway consignment note, road consignment note, truck or air waybill, or multimodal transport document, marked "freight prepaid" and showing delivery through to final destination as per the Schedule of Requirements;

(iii) four copies of the packing list identifying contents of each package;

(iv) copy of the Insurance Certificate, showing the Purchaser as the beneficiary;

(v) one original of the manufacturer's or Supplier's Warranty Certificate covering all items supplied;

(vi) one original of the Supplier's Certificate of Origin covering all items supplied;

(vii) original copy of the Certificate of Inspection furnished to Supplier by the nominated inspection agency and six copies (where inspection is required);

(viii) any other procurement-specific documents required for delivery/payment purposes.

For contraceptives from within the Purchaser's country:

Upon or before delivery of the contraceptives, the Supplier shall notify the Purchaser in writing and deliver the following documents to the Purchaser:

(i) two originals and two copies of the Supplier's invoice, showing Purchaser, the Contract number, contraceptives' description, quantity, unit price and total amount. Invoices must be signed in original and stamped or sealed with the company stamp/ seal;

(ii) two copies of delivery note, railway consignment note, road consignment note, truck or air waybill, or multimodal transport document showing Purchaser as [enter correct name of Purchaser for customs purposes] and delivery through to final destination as stated in the Contract;

(iii) copy of the Insurance Certificate, showing the Purchaser as the beneficiary;

(iv) four copies of the packing list identifying contents of each package;

(v) one original of the manufacturer's or Supplier's Warranty certificate covering all items supplied;

(vi) one original of the Supplier's Certificate of Origin covering all items supplied;

(vii) original copy of the Certificate of Inspection furnished to Supplier by the nominated inspection agency and six copies (where inspection is required);

(viii) other procurement-specific documents required for delivery/payment purposes.

Note: In the event that the documents presented by the Supplier are not in accordance with the Contract, then payment will be made against issue of the Acceptance Certificate, to be issued in accordance with SCC 8 (GCC 8) above.

GCC 11.1

The insurance shall be in an amount equal to 110 percent of the CIF or CIP value of the contraceptives from "warehouse" to "warehouse" on "All Risks" basis, including war risks and strikes (only if contract placed on CIF or CIP basis).

GCC 13.1
Incidental services to be provided are:

[Sample clauses]

(a) The Supplier shall provide all necessary licenses and permissions for use of the contraceptives in the Purchaser's country that may be required for the contraceptives. The cost shall be deemed included in the Contract Price.

(b) The Supplier shall provide such other services as are stated in the Technical Specifications. [insert: sections of the Technical Specifications where the services are listed.]

GCC 14.4
The period for the replacement of defective contraceptives is: [insert period for replacement of defective contraceptives].

GCC 15.1 & 15.4
[Sample provision]

The method and conditions of payment to be made to the Supplier under this Contract shall be as follows:

Payment for contraceptives supplied from abroad:

Payment of foreign currency portion shall be made in [insert: currency of the Contract Price] in the following manner:

(i) Advance Payment: Ten (10) percent of the Contract Price shall be paid within thirty (30) days of signature of Contract and receipt of the Performance Guarantee, upon submission of an invoice (showing Purchaser's name; the Contract number, loan number; description of payment and total amount, signed in original, stamped or sealed with the company stamp/seal) and a bank guarantee in the form provided in Section VIII, Advance Payment Bank Guarantee.

(ii) On Shipment: Eighty (80) percent of the Contract Price of the contraceptives shipped shall be paid through irrevocable confirmed letter of credit opened in favour of the Supplier in a bank in its country, upon submission of documents specified in GCC Clause 11 or, alternatively, at the Supplier's option, within thirty (30) days of submission of documents specified in GCC Clause 11 above by direct bank transfer to the Supplier's nominated bank account. Opening charges and charges for amendment of the letter of credit at the request of or due to a fault or default of the Purchaser are for the account of the Purchaser. Confirmation charges and charges for amendment to letters of credit at the request of or due to a fault or default on behalf of the Supplier are for the account of the Supplier.

(iii) On Acceptance: Ten (10) percent of the Contract Price of contraceptives received shall be paid within thirty (30) days of receipt of the contraceptives upon submission of an

invoice (showing Purchaser's name; the Contract number, loan number; description of payment and total amount, signed in original, stamped or sealed with the company stamp/seal) supported by the Acceptance Certificate issued by the Purchaser.

Payment of local currency portion shall be made in [insert: currency] within thirty (30) days of presentation of an invoice (showing Purchaser's name; the Contract number, loan number; description of payment and total amount, signed in original, stamped or sealed with the company stamp/seal) supported by the Acceptance Certificate issued by the Purchaser.

Payment for contraceptives and Services supplied from within the Purchaser's country:

Payment for contraceptives and Services supplied from within the Purchaser's country shall be made in [insert: currency], as follows:

(i) Advance Payment: Ten (10) percent of the Contract Price shall be paid within thirty (30) days of signature of Contract and receipt of the Performance Guarantee, upon submission of an invoice (showing Purchaser's name; the Contract number, loan number; description of payment and total amount, signed in original, stamped or sealed with the company stamp/seal) and a bank guarantee in the form provided in Advance Payment Bank Guarantee.

(ii) On Shipment: Eighty (80) percent of the Contract Price of the contraceptives shipped shall be paid within 30 days of submission of documents specified in GCC Clause 10 above by direct bank transfer to the Supplier's nominated bank account.

(iii)On Acceptance: Ten (10) percent of the Contract Price of contraceptives received shall be paid within thirty (30) days of receipt of the contraceptives upon submission of an invoice (showing Purchaser's name; the Contract number, loan number; description of payment and total amount, signed in original, stamped or sealed with the company stamp/seal) supported by the Acceptance Certificate issued by the Purchaser.

[Please note that percentages may be changed to meet procurement specific requirements or trade norms.]

GCC 16.1

[Sample provision]

Prices shall be fixed and firm for the duration of the Contract.

GCC 21.1

[insert: applicable rate]

[insert: maximum deduction]

Note: Applicable rate shall not exceed one-half (0.5) percent per week, and the maximum shall not exceed ten (10) percent of the Contract Price.

GCC 26.2.2

The dispute resolution mechanism to be applied pursuant to GCC Sub-Clause 26.2.2 shall be as follows:

(a) Contracts with foreign Supplier:

[For Contracts entered into with foreign Supplier, international commercial arbitration may have practical advantages over other dispute settlement methods. The World Bank should not be named as arbitrator, nor should it be asked to name an arbitrator. Among the rules to govern the arbitration proceedings, the Employer may wish to consider the United Nations Commission on International Trade Law (UNCITRAL) Arbitration Rules of 1976, the Rules of Conciliation and Arbitration of the International Chamber of Commerce (ICC), the Rules of the London Court of International Arbitration or the Rules of Arbitration Institute of the Stockholm Chamber of Commerce.]

If the Purchaser chooses the UNCITRAL Arbitration Rules, the following sample clause should be inserted:

GCC 26.2.2 (a˜) Any dispute, controversy or claim arising out of or relating to this Contract, or breach, termination or invalidity thereof, shall be settled by arbitration in accordance with the UNCITRAL Arbitration Rules as at present in force.

If the Purchaser chooses the Rules of ICC, the following sample clause should be inserted:

GCC 26.2.2 (a˜) All disputes arising in connection with the present Contract shall be finally settled under the Rules of Conciliation and Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with said Rules.

If the Purchaser chooses the Rules of Arbitration Institute of Stockholm Chamber of Commerce, the following sample clause should be inserted:

GCC 26.2.2 (a˜) Any dispute, controversy or claim arising out of or in connection with this Contract, or the breach, termination or invalidity thereof, shall be settled by arbitration in accordance with the Rules of the Arbitration Institute of the Stockholm Chamber of Commerce.

If the Purchaser chooses the Rules of the London Court of International Arbitration, the following clause should be inserted:

GCC 26.2.2 (a˜) Any dispute arising out of or in connection with this Contract, including any question regarding its existence, validity or termination shall be referred to and finally resolved by arbitration under the Rules of the London Court of International Arbitration, which rules are deemed to be incorporated by reference to this clause.

(b) Contracts with Supplier national of the Purchaser's country:

In the case of a dispute between the Purchaser and a Supplier who is a national of the Purchaser's country, the dispute shall be referred to adjudication or arbitration in accordance with the laws of the Purchaser's country.

[The bidding documents should contain one clause to be retained in the event of a Contract with a foreign Supplier and one clause to be retained in the event of a Contract with a Supplier who is a national of the Purchaser's country. At the time of finalizing the Contract, the respective applicable clause should be retained in the Contract. The following explanatory note should, therefore, be inserted as a header to SCC 26.2.2 in the bidding document.

"Clause 26.2.2 (a) shall be retained in the case of a Contract with a foreign Supplier and Clause 26.2.2 (b) shall be retained in the case of a Contract with a national of the Purchaser's country."]

GCC 28.1 [insert: the governing language]

GCC 29.1 The Contract shall be interpreted in accordance with the laws of the:

[insert: name of country].

GCC 30.1 [insert: the Purchaser's address for notice purposes]

[insert: the Supplier's address for notice purposes]

Special Conditions of Contract: Pharmaceuticals

(Additional Clauses)

The below data should be included in the Special Conditions of Contract used in Bidding Documents for the procurement of pharmaceuticals.

GCC 10.1 & 10.3
For contraceptives supplied from abroad:

(ix) One original of the Certificate of Pharmaceutical Product as recommended by the WHO for each of the items supplied.

(x) Certificate of quality control test results in conformity with the World Health Organization "Certification Scheme on the Quality of Pharmaceutical Products Moving in International Trade" stating quantitative assays, chemical analysis, sterility, pyrogen content, uniformity, microbial limit and other tests as appropriate to the contraceptives.

(xi) Original copy of the certificate of weight issued by the port authority/licensed authority and six copies.

Special Conditions of Contract: Condoms

The following Special Conditions of Contract shall supplement the General Conditions of Contract in the procurement of condoms. Whenever there is a conflict, the provisions herein shall prevail over those in the General Conditions of Contract. The corresponding clause number of the GCC is indicated in parentheses.

GCC 8(d)
The Supplier shall test batches of contraceptives ready for shipment in accordance with the WHO specification. The size of the sample for testing will be calculated by reference to ISO2859-1. With each consignment, the Supplier must provide a certificate of quality control test results in conformity with the standards laid down in ISO 2859-1 and in accordance with the general sampling levels appropriate to each feature as necessary. The Supplier will bear the cost of such tests.

GCC 10.1 & 10.3
For contraceptives supplied from abroad:

(ix) original copy of quality control tests for each consignment as stated in SCC 8 above.

(x) original copy of the certificate of inspection furnished to Supplier by nominated inspection agency and six copies [where separate inspection is required].

For contraceptives from within the Purchaser's country:

(ix) certificate of in-house analysis.

Notes for Preparing the Schedule of Requirements

The Schedule of Requirements provides a concise description of each product and the quantity required, along with any technical specifications unique to that item. If it can be printed with sufficient space for Suppliers to enter offers, having Suppliers use this space for bids greatly simplifies the collation of offers. Sufficient space should be provided so that the Supplier can enter all relevant information, including the name of the original manufacturer.

The Schedule of Requirements should include the international non-proprietary name (INN) or generic name (for combination product, the name of each generic component), the strength in metric units for each component, the basic unit (tablet, capsule, vial, bottle), the package size and the number of packages needed. Some Schedules of Requirements list both the total number of packages and the total number of basic units needed to avoid misunderstanding and to allow for the possibility that a Supplier may offer a different (but acceptable) package size representing the same number of basic units. The schedule of requirements should specify whether the listed package sizes are the only ones acceptable.

The delivery schedule expressed as weeks stipulates hereafter a delivery date that is the date of delivery (i) at EXW premises, or (ii) to the carrier at the port of shipment when the Contract is placed on FOB or CIF terms or (iii) to the first carrier when the Contract is placed on FCA or CIP terms. To determine the correct date of delivery hereafter specified, the Purchaser has taken into account the additional time that will be needed for international or national transit to the site or to another common place.

SCHEDULE OF REQUIREMENTS

Product Strength	**A** *xx*	**B** *xx*	**C** *xx*	**D** *xx*
Quantity in Doses				
Date for Delivery				
No. of Shipments				
Shelf Life*				

* remaining on delivery date

PRICE OFFER

Product	**A**	**B**	**C**	**D**

Please enter prices in US dollars in appropriate boxes.

Period of Validity: .....

Signature: .....

Date: .....

For: .....
(name of company)

Information About Technical Specifications – General

Technical specifications are one of the most important elements of procurement:

- They provide detailed information to bidders about the goods to be purchased.
- They are the benchmarks against which the purchaser will judge the technical responsiveness of bids.
- They form the basis for the contractual obligation of the supplier to the purchaser.
- They are the criteria against which the purchaser will determine the acceptability of specific goods prepared by the seller for shipment.

Technical specifications must be clear, accurate and complete; otherwise, the procurement will not be able to proceed on schedule and the entire procurement process may need to be cancelled:

- Questions raised by bidders can force the procuring entity to push back the deadline for bid submission to accommodate amendments to the bidding documents.
- A significant number of bidders may misunderstand the requirements and quote items that do not meet programme needs, forcing the procuring entity to reject all bids and re-start the process.
- It may be impossible for the evaluation committee to correctly identify a winning bid, and if one is chosen for any other reason than what is specifically stated in the bidding documents, bidder protests may result, which can create delays in the procurement process.
- Goods that do not meet programme needs may be delivered because the supplier is under no obligation to supply goods other than what is specifically described in the bidding documents.

Under any of the above scenarios, time and resources will be wasted: at a minimum, the delivery schedule will be delayed. Further up the consequence scale, needs will not be met, legal problems may ensue, mis-procurement may be declared and funding may be lost.

In addition to specifications that are clear, accurate and complete, public sector procurement requires that specifications be prepared in a way that will encourage maximum competition. They must be "product neutral". In other words, they must use generic terms, relative characteristics and performance requirements rather than brand names and superficial descriptions. If there is no way to avoid stating a brand name, it must be followed by "or equivalent". Non-functional requirements such as colour and exact dimensions must have strong justification and may not be used simply to eliminate all but a specific brand.

Specifications must be written in industry-standard vocabulary so there is no question about what is required. Contraceptives and pharmaceuticals can be described in scientific terms with reference to a specific pharmacopoeia. Medical devices can be described according to

a system developed in the European Community which is used in the US and some other countries as well, the Global Medical Device Nomenclature (GMDN). The use of standard nomenclature eliminates misunderstanding and miscommunication due to variation in the use of terms (in English) by different countries and through translations from other (main) languages.

Specifications are not just about the physical product in terms of technical and performance characteristics, size, units and quantity, but should also include a description of:

- Intended use
- Packaging and marking
- Packing and shipping marks
- Regulatory requirements
- Standards and required certifications
- Quality assurance criteria including detailed tests required
- Acceptance criteria
- Detailed activities to be performed by the supplier
- Documentation

How to obtain appropriate specifications, and/or who should prepare them can be a challenge for the procurement unit. Considering the depth of knowledge and specialized information required for writing effective, unambiguous procurement specifications, it is a job best done by a person with specific technical expertise. Line Directors and end users are aware of their requirements from the standpoint of using a product, but they are not usually the best authority on how the product is put together. In addition, they may not be familiar with the scientific terms needed to accurately describe it.

The role of procurement staff in specification development includes gathering information, facilitating communication between technical personnel and end users, consulting with the technical expert, and placing the completed specification in the bidding documents. Actually writing specifications is not a job for procurement officers.

Specifications that have been developed in the past and preserved in a file or database for future use are very convenient; however, a technical expert should be asked to review them to make sure they accurately and completely reflect the current requirement before they are adopted for use in a procurement action.

B. Sample Technical Specifications for Contraceptives

This section contains sample technical specifications for contraceptives that can be used by procurement staff when conducting local or international competitive procurement. It is always beneficial to have any technical specification reviewed before release by a technical expert as discussed above.

In the following specifications, examples of actual product specifications are in italics. When preparing procurement specifications, appropriate product specifications should be substituted for the italicized examples. This sample is designed to be used in conjunction with bidding and contract documents.

The following checklist can be used as a guide in preparing or reviewing a contraceptive technical specification to ensure that all of the key components of a contraceptive specification have been included in the document.

Checklist of Elements for Inclusion in Specifications for Pharmaceuticals and Contraceptives

- ☐ **Description:** Generic name (INN); Type of product; Intended use
- ☐ **Formulation (drug content):** Pills & Injectables
- ☐ **Registration number**
- ☐ **Drug Manufacturing License Number**
- ☐ **Materials:** Condoms & IUDs
- ☐ **Presentation:** Dosage form; Dosage size
- ☐ **Filling Volume (as applicable)**
- ☐ **Identification (markings):** Marking/labelling of product
- ☐ **Primary Packaging:** Materials and description; Package layout/dimensions; Markings; Special labelling/logo (if desired)
- ☐ **Overpacking (cartons):** Materials and description; Markings
- ☐ **Exterior Packing (for shipping):** Materials and description; Markings
- ☐ **Shelf Life:** In months or years; Stability/storage temperature; Months remaining upon receipt in-country
- ☐ **Printed Materials:** Language; Patient inserts; Physician inserts; Special instructions
- ☐ **Regulatory Requirements**
- ☐ **Quality Assurance Requirements:** Pharmacopoeia standard (if applicable)
- ☐ **Documentation:** Test data; Certificate of Analysis; Regulatory certificates
- ☐ **Quality Compliance Provisions:** Preshipment inspection (of physical attributes); Preshipment sampling and testing (for analysis of suspect products)

Technical Specification - Oral Contraceptive

Information for submission of samples

The sample oral contraceptives submitted by the Bidder in response to this Invitation for Bids must be exactly the same[1] as would be supplied if a contract were awarded to the Bidder. The packets containing the product need not have a printed logo as stipulated under Clause 1.12 of this specification; however, other information as stipulated under the aforementioned clause must be furnished. For sample submission only, this information (logo optional) may be printed on a sticker and affixed to the packets containing the product. The purchaser should replace italics with the actual requirements of the contraceptive to be procured.

1. Requirements

Oral contraceptive tablets in accordance with the following specifications:

- *Twentyeight (28)-day cycle package consisting of twentyone (21) oral contraceptive norgestrel and ethinylestradiol tablets and seven (7) ferrous fumarate tablets.*

Contraceptive tablets: 21

Each tablet shall contain 0.03 mg of ethinylestradiol and 0.3 mg of norgestrel.

Spacing tablets: 7

Each tablet shall contain 75 mg ferrous fumarate.

1.1 Product and Brand Names

Product name: .....

Brand names: .....

Registration Number: .....

1.2 Raw Materials

Oral contraceptives offered under this purchase description shall be produced from validated raw materials obtained from a licensed manufacturer or its authorized distributor.[2]

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[1] For example, same tablet shape, colour, weight, ingredients and identification imprint; same blister pack size, material, text and identification markings; same inner box size, material, text and identification markings.

[2] Because the raw materials that make up both active and inactive ingredients are of great importance for final product bioavailability and stability, current good manufacturing practices require that manufacturers validate vendors for all raw materials. A typical validation includes, but is not limited to, these areas:

- Manufacturing records and procedures for raw materials synthesis, processing, packing and storage.
- Quality control records and procedures for the raw materials, in-process and final product.
- Plant certification by local regulatory authorities (such as commerce, industry, health, labour, environment) as required.
- Certification of workers' training in current good manufacturing practices and safety protection.
- Records demonstrating raw materials with the required physical and chemical characteristics.

1.3 Registration Requirements
Oral contraceptives offered under this purchase description shall be currently registered in Pakistan and approved by the Ministry of Health under the Drugs Act, 1976.

1.4 Certificate of Registration Status in Country of Origin (in case of imported drugs)
Oral contraceptives offered under this purchase description shall be licensed for marketing by the drug regulatory authority of the country of origin. Prior to award of the Contract, the successful offeror(s) may be required to submit a "statement of licensing status of pharmaceutical product(s)" as provided under the World Health Organization (WHO) Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.[3]

1.5 Compliance With Current Good Manufacturing Practices
The Supplier must be able to provide certification that the oral contraceptives are manufactured according to WHO current good manufacturing practices (cGMPs). Such certification can be found in the WHO Certification Scheme "Certificate of Pharmaceutical Product." Supplier also must be able to provide copies of its annual cGMP audit reports conducted by the local Drug Regulatory Authority.

1.6 WHO Certification—Movement in International Commerce
The Supplier must be able to provide documentation indicating that the manufacturer of the product has received confirmation from the Ministry of Health of the country of manufacture that the pharmaceutical meets the requirements in the WHO Certification Scheme.

1.7 Shape and Dimensions
Tablets shall be of the shape and dimensions of the Bidder's normal, standard commercial tablets which are available in the local market.

1.8 Colours
Contraceptive and ferrous fumarate (or inert, if applicable) tablets shall be similar to Bidder's normal, standard commercial tablets.

1.9 Tablet Markings
Each tablet shall bear the identifying imprint of its manufacturer.

1.10 Packaging

1.10.1 Monthly Cycle Presentation
Each individual tablet shall be enclosed in a transparent blister pack of thermoformed polymer, with a minimum thickness of 0.1905 mm (.0075 inch) backed with aluminum foil, minimum thickness 0.0178 mm (0.0007 inch). Variations must be proven scientifically comparable by means of stability data.

[3] Available at: http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/en/index.html.

The size of the package shall not be less than 57.15 mm (2.25 inches) x 82.55 mm (3.25 inches). Thicker polymer or foil or the addition of a card to either the front or the back of the package (in addition to the minimum polymer or foil) is acceptable.

1.10.2 Mounting

Tablets shall be mounted on four (4) rows of seven (7) tablets per row. Contraceptive tablets shall precede the ferrous fumarate tablets (or inert tablets, if applicable).

1.11 Identification Markings on Individual Blister Packs

Each individual blister pack shall have the following information:

- Product/brand name
- Lot/batch number
- Expiration date (day, month and year)
- Date of manufacture
- Manufacturer's name and address
- Arrow indicating sequence of tablets
- Contents and quantity, including tablet formulation (amounts of active ingredients per tablet)
- Drug registration number (if applicable)
- Family planning logo (if applicable)
- Drug Manuafacturing License Number
- Product use and storage instructions (accompanying the blister pack).

1.11.1 Printing and Layout

On the front of each monthly cycle above the first row of tablets and in the left-hand corner, the trade or brand name of the product shall be printed in full. In parentheses, in reduced lettering (smallest type no less than 1 mm high) and below the product or brand name, shall be printed "Family Planning Pills." Sequence of administration shall be clearly indicated by an arrow/line pathway on the unit.

The day, month and year of expiration shall be shown in the following format DD/MM/YY. The lot/control number shall be shown in English numerals. Debossing is acceptable for these numbers.

The tablet formulation and a "copy control code" (evidence that artwork/packaging has been approved by all parties) shall be printed on the individual packet and may be printed on the reverse side (smallest type no less than 1 mm high).

1.11.2 Colour

Background colour shall be the natural colour of the aluminum foil on the face, with a dark blue (PMS Blue 301) stripe across the top and the "Blue Lady" symbol depicted to

the right but within the blue stripe. The reverse of the individual packet will not be inked except for necessary printing.

1.12 Workmanship

Products and packaging shall be free of defects that impair their serviceability, affect their durability, or detract from their appearance.

1.13 Lots Per Order

The Supplier shall fill the order using the fewest number of manufacturing lots possible.

1.14 Shelf Life

The shelf life of the product provided under this solicitation shall be *five (5) years* from the date of manufacture when stored under tropical conditions such as those prevailing in the local environment. The Supplier shall be able to provide to the satisfaction of the registration/national quality control authorities the manufacturer's stability test data substantiating this *five (5) year* shelf life at ambient temperatures at or greater than 32 degrees Celsius and at a relative humidity of 85% in the proposed blister package.

At the time of inspection or acceptance for delivery to the country of destination, no more than *nine (9) months* shall have expired since the date of manufacture shown on the batch release or Certificate of Analysis.

1.16 Test Data

Chemical and physical test data for raw materials, components in-process and finished product testing must be on record for each lot manufactured and must be available to Purchaser's representatives when requested.

2. Quality Assurance Provisions

2.1 Compliance

The Supplier shall guarantee that the products as packed for supply comply with all provisions of the specifications and related documents.

2.2 Documentation

2.2.1 The Supplier shall provide evidence[4] of the satisfaction of the technical specification requirements for which specific inspection instructions or protocols have not been provided. Such evidence is contained in the "Manufacturer's Batch Certificate" under the WHO Certification Scheme.

2.2.2 The Supplier shall provide a copy of the manufacturing record and procedures to the Purchaser for each lot intended for supply.

2.2.3 The Supplier shall provide a copy of the Certificate of Analysis to the Purchaser for each lot intended for supply.

[4] Evidence includes quality control and manufacturing records, in-process control records and final product Certificate of Analysis.

2.2.4 The Supplier shall provide to the Purchaser a copy of the approval of each component for each lot intended for supply.

2.3 Inspection by the Purchaser

The Purchaser reserves the right to perform or cause to be performed any of the inspections and tests set forth in the Technical Specifications and Special Conditions of Contract to ensure that the goods conform to prescribed requirements. The Purchaser reserves the right, and/or may assign the right to a representative, to enter and inspect the production facility prior to supply of the goods and to draw samples from the Supplier's factory and/or warehouse for test analysis. Except as otherwise specified in the Contract or purchase order, prior to supply, the Purchaser will sample, or cause to be sampled, the product as packed in inner boxes preparatory to packing in exterior shipping cartons. The sampling shall be according to recognized standards.[5]

The Purchaser may have some or all of the tests specified in the Technical Specifications (Dossier) of the Contract performed by a laboratory suitably equipped and qualified to conduct quality assurance tests on pharmaceutical products according to the Pharmacopoeia specification.

2.4 Sampling Procedures

The Purchaser, or the Purchaser's representative, shall select the required samples from the lot according to the Special Conditions of Contract. If the order is to be filled using more than one production lot, each production lot shall be separately sampled and tested.

The normal, tightened and reduced inspection provisions of ISO 2859 (Inspection by Attributes) may be used for visual inspection. Sampling for analytical testing shall be done in accordance with pharmacopoeial requirements.

All sampled boxes and supply cartons shall be so marked and shall include the date and initials of the sampler.

2.5 Sample Retention

The Supplier shall retain a sample of ten (10) cycles, or the equivalent required to perform three (3) complete chemical assays, from each lot shipped, for a period of one (1) year after the printed expiration date.

[5] Depending on the tests required, sampling may be conducted according to the standards of the International Organization for Standardization (ISO 2859: Inspection by Attributes) (included as Appendix IVI.H), the report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (included as Appendix IVI.I), or as dictated by local or international pharmacopoeia. Following recognized sampling procedures helps to ensure that the products tested are representative of the whole.

3. Packing

3.1 Inner Boxes

3.1.1 Products sealed in individual packets as specified in Section 1.11 shall be packed in inner boxes of *one hundred (100) cycles*.[6]

Inner boxes shall be made of *light fibreboard (white)* of a size sufficient to contain the specified number of cycles. The overall dimensions should be such that the product does not get damaged during transportation and storage.

3.1.2 For inner boxes, the Bidder shall fill in the blanks provided below:

Each inner box will contain *one hundred (100) cycles*. The overall dimensions of a box will be ..... cm x ..... cm x ..... cm.

3.2 Exterior Shipping Cartons

3.2.1 *Product and printed materials, packaged and packed as specified above, shall be contained in triple-wall corrugated fibreboard cartons made from weather-resistant fibreboard with a bursting test strength of not less than 1,900 kPa. The carton flaps shall be secured with water-resistant adhesive applied to not less than 75% of the area of contact between the flaps or with 75 mm-wide water-resistant tape applied to the full length of the center seams and extending over the ends not less than 75 mm.[7] Plastic strapping shall be placed around the carton, with a minimum of two crossing bands. Cartons exceeding 760 mm (30 inches) in length shall have additional bands placed around the carton.*

3.2.2 The Bidder shall fill in the following blanks:

The exterior shipping carton will contain ..... inner boxes. The overall dimensions of a carton will be ..... cm x ..... cm x ..... cm, and the gross weight of one shipping carton will be ..... kg.

A standard 6.096-meter (20-foot) container will accommodate ..... exterior shipping cartons.

3.3 Markings

3.3.1 Inner Boxes

The inner boxes shall be marked with the following information in a clearly legible manner that is acceptable to the Purchaser[8]:

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[6] Sometimes oral contraceptives are packaged to contain three (3) cycles per inner box. If this is the preferred configuration, a three (3)-cycle-per-box packaging description should be detailed in the specification.

[7] The use of additional tape along the joint of the outer lids and around the top and bottom corners will greatly increase each carton's resistance to damage during shipment and storage. Tape can be made of plastic film, kraft paper, or fabric, either plain or reinforced with plastic threads.

[8] The smallest type shall be no less than 1 mm high, unless otherwise specified by the commercial laws of the country of importation.

- Product/brand name
- Drug Manufacturing License Number
- Lot/batch number
- Expiration date (day, month and year)
- Date of manufacture
- Manufacturer's name and address
- Contents and quantity
- Drug registration numbers (if applicable)
- Instructions for storage and handing

3.3.2 Exterior Supply Cartons

The following information shall be stenciled or labelled on the exterior supply cartons on two opposing sides in bold letters at least ..... mm high with waterproof ink in a clearly legible manner that is acceptable to the Purchaser.[9]

Regulatory information (on two opposing sides of carton)

- Product/brand name
- Drug Manufacturing License Number
- Lot/batch number
- Expiration date (day, month and year)
- Date of manufacture
- Manufacturer's name and address
- Contents and quantity
- Drug registration numbers (if applicable)
- Instructions and symbols for storage and handling, such as KEEP DRY or DO NOT FREEZE

Customs and shipping information (on two opposing sides of carton)

- Made in .....
- Supplier's name and address (if different from manufacturer)
- Consignee's address in full
- Gross weight of each carton (in kg)
- Port of entry
- Contract number
- Quantity of goods
- Carton ..... of .....

[9] The smallest type shall be no less than 10 mm high, unless otherwise specified by the commercial laws of the country of importation.

3.4 Printed Materials—Product Information Sheets

3.4.1 *Consumer information and directions for use shall be printed in English and/or in ..... and provided as package inserts, one copy for each consumer unit. All copies are to be accumulated, fastened together and included in each exterior supply carton.*

3.4.2 *Information for physicians' use shall be printed in English and/or in ..... Two copies of such information shall be provided for each one thousand two hundred (1,200) monthly cycles and shall be placed in each exterior supply carton.*

Inspection Sampling and Testing—Oral Contraceptives

Prior to shipment, the Purchaser or its appointed representative has the right to sample and inspect each consignment of oral contraceptives at the factory or Supplier's warehouse in accordance with ISO 2859 Inspection by Attributes (or WHO specifications) and Technical Specification of this Contract.

1.1 Packaging, Packing and Markings

a. One hundred percent (100%) of the exterior supply cartons will be examined for:

General physical characteristics and condition.

Markings per Technical Specification ..... .

b. *A representative sample of the inner boxes and individual packages will be drawn from the exterior supply cartons at General Inspection Level II, or, at the discretion of the Purchaser, General Inspection Level III, Single Sampling Plan for Normal Inspection.*

The sample will be examined for:

- General physical characteristics per Technical Specification ....., Section .....
- Markings per Technical Specification ....., Section .....

c. Inspection criteria and classification of defects shall follow the inspection guidelines outlined in Section 1.4 below. For critical defects, the acceptable quality limit (AQL) shall be 0%; for major defects, the AQL shall be 1%; for minor defects, the AQL shall be 4%.

1.2 Tablet

At the discretion of the Purchaser, part of the selected sample may be sent to a qualified government drug testing laboratory for physical and chemical testing as follows.

Pharmacopoeial tests:

- Identification
- Assay of active ingredient(s)
- Content uniformity
- Disintegration and/or dissolution
- Uniformity of mass (not required if content uniformity test performed)

Nonpharmacopoeial tests:

- Package seal integrity test.[10]

A Certificate of Analysis for production lot(s) shall be made available to the inspector and/or Purchaser upon request. The certificate shall state all tests performed, their specifications, and actual test results obtained. All pharmacopoeial test results shall meet applicable pharmacopoeial limits.

1.3 Resolution of Defects

a. Packaging, Packing, and Markings

Defects in exterior shipping carton markings must be corrected by the Supplier prior to supply.

All goods from corresponding production lots with inspection lot defect in excess of the AQLs listed in Section 1.4 of this specification must be corrected and reinspected at Supplier's expense or rejected.

b. Tablet

Any deviation from the manufacturer's Certificate of Analysis, product specifications, or relevant pharmacopoeial limits shall result in rejection of goods from the entire production lot.

Technical Specifications - Injectable Contraceptives

Information for Submission of Samples

The sample injectable contraceptives submitted by the Bidder in response to this Invitation for Bids must be exactly the same as would be supplied if a contract were awarded to the Bidder.[11] The vial or ampoule containing the product need not have a printed logo; however, other information as stipulated under Clause 1.11 of this specification must be furnished. For sample submission only, this information (logo optional) may be printed on a sticker and

[10] Immerse package in 0.05 percent methylene blue solution under 15 vacuum gauge for two minutes. Observe for leakage. AQL 2.5%.

[11] For example, vials or ampoules must be of the same glass type, closure type, colour, size, text and identification markings; contents must have same ingredients, colour and weight; same inner box size, material, text and identification markings.

affixed to the vials or ampoules containing the product. The purchaser should replace italics with the actual requirements of the contraceptive to be procured.

1. Requirements

Injectable contraceptives in accordance with the following specifications:

- *Long-acting progestin in sterile aqueous suspension for intramuscular injection once every three (3) months.*
- *Each 1-ml vial or ampoule should contain a minimum of 1.1 ml of sterile aqueous suspension containing 150 mg/ml medroxyprogesterone acetate.*

1.1 Product and Brand Names

Product name: .....

Brand names: .....

Registration number: .....

Drug Manufacturing License Number .....

1.2 Raw Materials

Injectable contraceptives offered under this purchase description shall be produced from validated raw materials obtained from a licensed manufacturer or its authorized distributor.[12]

1.3 Primary Packaging Requirements

Injectable contraceptives offered under this purchase description shall be packaged in vials or ampoules that meet quality standards as specified in ISO 8362-1. Closures for injection vials shall meet quality standards as specified in ISO 8362-2.

1.4 Registration Requirements

Injectable contraceptives offered under this purchase description shall be currently registered in Pakistan and approved by the Ministry of Health under the Drugs control Act 1976. ..... *(local regulatory authority).*

1.5 Certificate of Registration Status in Country of Origin (in case of imported drugs)

Injectable contraceptives offered under this purchase description shall be licensed for

[12] Because the raw materials that make up both active and inactive ingredients are of great importance for final product bioavailability and stability, current good manufacturing practices require that manufacturers validate vendors for all raw materials. A typical validation includes, but is not limited to, these areas:

- Manufacturing records and procedures for raw materials synthesis, processing, packing and storage.
- Quality control records and procedures for the raw materials, in-process and final product.
- Plant certification by local regulatory authorities (such as commerce, industry, health, labour, environment) as required.
- Certification of workers' training in current good manufacturing practices and safety protection.
- Records demonstrating raw materials with the required physical and chemical characteristics.

marketing by the drug regulatory authority of the country of origin. Prior to award of the Contract, the successful offeror(s) may be required to submit a "statement of licensing status of pharmaceutical product(s)" as provided under the World Health Organization (WHO) Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.[13]

1.6 Compliance with Current Good Manufacturing Practices

The Supplier must be able to provide certification that the injectable contraceptives are manufactured according to WHO current good manufacturing practices (cGMPs). Such certification can be found in the WHO Certification Scheme "Certificate of Pharmaceutical Product". Supplier also must be able to provide copies of its annual cGMP audit reports conducted by the local Drug Regulatory Authority.

1.7 WHO Certification—Movement in International Commerce

The Supplier must be able to provide documentation indicating that the manufacturer of the product has received confirmation from the Ministry of Health of the country of manufacture that the pharmaceutical meets the requirements in the WHO Certification Scheme.

1.8 Appearance

Injectable contraceptives shall appear as an aqueous white suspension contained in 1-ml or 10-ml glass vials or 1-ml glass ampoules.

1.9 Filling Volume

Each 1-ml glass vial or ampoule shall contain a minimum of 1.1 ml of sterile aqueous suspension.

Each 10-ml glass vial shall contain a minimum of 10.5 ml of sterile aqueous suspension.

1.10 Identification Markings on Individual Vials or Ampoules

Each individual vial or ampoule shall have the following information:

- Product/brand name
- Lot/batch number
- Expiration date (day, month and year)
- Date of manufacture
- Manufacturer's name and address
- Presentation (e.g., *sterile aqueous suspension*)

[13] Available at: http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/en/index.html.

- Formulation (amounts of active ingredients per vial or ampoule)
- Drug registration number (if applicable)
- Family planning logo (if applicable)

If space allows, the following information shall also appear on each individual vial or ampoule:

- Recommended storage conditions.
- Drug Manufacturing License Number.

1.11 Workmanship

Products and packaging shall be free of defects that impair their serviceability, affect their durability or detract from their appearance.

1.12 Lots Per Order

The Supplier shall fill the order using the fewest number of manufacturing lots possible.

1.13 Shelf Life

The shelf life of the product provided under this solicitation shall be at least *three (3) years* from the date of manufacture when stored under tropical conditions such as those prevailing in the local environment. The Supplier shall be able to provide to the satisfaction of the registration/national quality control authorities the manufacturer's stability test data substantiating this *three (3) year* shelf life at ambient temperatures at or greater than 32 degrees Celsius and at a relative humidity of 85% in the proposed vial or ampoule.

At the time of inspection or acceptance for delivery to the country of destination, no more than *nine (9) months* shall have expired since the date of manufacture shown on the batch release or Certificate of Analysis.

1.14 Test Data

Chemical, physical and microbiological test data for raw materials, components in-process and finished product testing must be on record for each lot manufactured and must be available to Purchaser's representatives when requested.

2. Quality Assurance Provisions

2.1 Compliance

The Supplier shall guarantee that the products as packed for supply comply with all provisions of the specifications and related documents.

2.2 Documentation

2.2.1 The Supplier shall provide evidence[14] of the satisfaction of the technical specification requirements for which specific inspection instructions or protocols have not been provided. Such evidence is contained in the "Manufacturer's Batch Certificate" under the WHO Certification Scheme.

2.2.2 The Supplier shall provide a copy of the manufacturing record and procedures to the Purchaser for each lot intended for supply.

2.2.3 The Supplier shall provide a copy of the Certificate of Analysis to the Purchaser for each lot intended for supply.

2.2.4 The Supplier shall provide to the Purchaser a copy of the approval of each component for each lot intended for supply.

2.3 Inspection by the Purchaser

The Purchaser reserves the right to perform or cause to be performed any of the inspections and tests set forth in the Technical Specifications and Special Conditions of Contract to ensure that the goods conform to prescribed requirements. The Purchaser reserves the right, and/or may assign the right to a representative, to enter and inspect the production facility prior to supply of the goods and to draw samples from the Supplier's factory and/or warehouse for test analysis. Except as otherwise specified in the Contract or purchase order, prior to shipment, the Purchaser will sample, or cause to be sampled, the product as packed in inner boxes preparatory to packing in exterior shipping cartons. The sampling shall be according to recognized standards.[15]

The Purchaser may have some or all of the tests specified in the Technical Specifications of the Contract performed by a laboratory suitably equipped and qualified to conduct quality assurance tests on pharmaceutical products according to Pharmacopoeia specifications.

2.4 Sampling Procedures

The Purchaser or the Purchaser's representative shall select the required samples from the lot according to the Special Conditions of Contract. If the order is to be filled using more than one production lot, each production lot shall be separately sampled and tested.

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[14] Evidence includes quality control and manufacturing records, in-process control records and final product Certificate of Analysis.

[15] Depending on the tests required, sampling may be conducted according to the standards of the International Organization for Standardization (ISO 2859: Inspection by Attributes) (included as Appendix IVI.H), the report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (included as Appendix IVI.I), or as dictated by local or international pharmacopoeia. Following recognized sampling procedures helps to ensure that the products tested are representative of the whole.

The normal, tightened and reduced inspection provisions of ISO 2859 (Inspection by Attributes) may be used for visual inspection. Sampling for analytical testing shall be done in accordance with pharmacopoeial requirements.

All sampled boxes and supply cartons shall be so marked and shall include the date and initials of the sampler.

2.5 Sample Retention

The Supplier shall retain a sample of ten (10) vials or ampoules, or the equivalent required to perform three (3) complete chemical assays, from each lot shipped, for a period of one (1) year after the printed expiration date.

3. Packing

3.1 Inner Boxes

3.1.1 *One hundred (100) individual glass vials or ampoules* will be contained in sturdy white cardboard boxes outfitted with individual segments for protecting and separating each vial or ampoule.

Inner boxes shall be made of sturdy white cardboard of a size sufficient to contain the specified number of vials or ampoules. The overall dimensions should be such that the product does not get damaged during transportation and storage.

3.1.2 For inner boxes, the Bidder shall fill in the blanks provided below:

Each inner box will contain *one hundred (100) units*. The overall dimensions of a box will be ..... cm x ..... cm x ..... cm.

3.2 Exterior Shipping Cartons

3.2.1 *Product and printed materials, packaged and packed as specified above, shall be contained in triple-wall corrugated fibreboard cartons made from weather-resistant fiberboard with a bursting test strength of not less than 1,900 kPa. The carton flaps shall be secured with water-resistant adhesive applied to not less than 75% of the area of contact between the flaps or with 75 mm-wide water-resistant tape applied to the full length of the center seams and extending over the ends not less than 75 mm.*[16] *Plastic strapping shall be placed around the carton, with a minimum of two crossing bands. Cartons exceeding 760 mm (30 inches) in length shall have additional bands placed around the carton.*

3.2.2 Additional cushioning shall be provided as needed to protect the vials or ampoules from breakage during transit and handling.

[16] The use of additional tape along the joint of the outer lids and around the top and bottom corners will greatly increase each carton's resistance to damage during shipment and storage. Tape can be made of plastic film, kraft paper, or fabric, either plain or reinforced with plastic threads.

3.2.3 The Bidder shall fill in the following blanks:

The exterior shipping carton will contain ..... inner boxes. The overall dimensions of a carton will be ..... cm x ..... cm x ..... cm, and the gross weight of one shipping carton will be ..... kg.

A standard 6.096-meter (20-foot) container will accommodate ..... exterior shipping cartons.

3.3 Markings

3.3.1 Inner Boxes

The inner boxes shall be marked with the following information in a clearly legible manner which is acceptable to the Purchaser[17]:

- Product/brand name
- Drug manufacturing License number
- Lot/batch number

- Expiration date (day, month and year)
- Date of manufacture
- Manufacturer's name and address
- Contents and quantity
- Drug registration number (if applicable)
- Instructions for storage and handing
- Formulation and presentation

3.3.2 Exterior Shipping Cartons

The following information shall be stenciled or labelled on the exterior shipping cartons on two opposing sides in bold letters at least ..... mm high with waterproof ink in a clearly legible manner that is acceptable to the Purchaser.[18]

Regulatory information (on two opposing sides of carton)

- Product/brand name
- Drug manufacturing License Number
- Lot/batch number
- Expiration date (day, month and year)

[17] The smallest type shall be no less than 1 mm high, unless otherwise specified by the commercial laws of the country of importation.

[18] The smallest type shall be no less than 10 mm high, unless otherwise specified by the commercial laws of the country of importation.

- Date of manufacture
- Manufacturer's name and address
- Contents and quantity
- Drug registration numbers (if applicable)
- Instructions and symbols for storage and handling, such as KEEP DRY or DO NOT FREEZE.

Customs and shipping information (on two opposing sides of carton)

- Made in.....
- Supplier's name and address (if different from manufacturer)
- Consignee's address in full
- Gross weight of each carton (in kg)
- Port of entry
- Contract number
- Quantity of goods
- Carton ..... of .....

3.4 Printed Materials—Product Information Sheets

Twenty (20) patient information sheets and one (1) prescribing information sheet, printed in English and/or in .....…, shall be included in each intermediate container.

Inspection Sampling and Testing—Injectable Contraceptives

Prior to shipment, the Purchaser or its appointed representative has the right to sample and inspect each consignment of injectable contraceptives at the factory or Supplier's warehouse in accordance with ISO 2859 Inspection by Attributes (or WHO specifications) and Technical Specification ..... of this Contract.

1.1 Packaging, Packing and Markings

a. One hundred percent (100%) of the exterior shipping cartons will be examined for:
   - General physical characteristics and condition
   - Markings per Technical Specification .....

b. *A representative sample of the inner boxes and individual vials or ampoules will be drawn from the exterior shipping cartons at General Inspection Level II, or, at the discretion of the Purchaser, General Inspection Level III, Single Sampling Plan for Normal Inspection.*

The sample will be examined for:

- General physical characteristics per Technical Specification ....., Section .....
- Markings per Technical Specification ....., Section .....

c. Inspection criteria and classification of defects shall follow the inspection guidelines outlined in Section 1.4 below. For critical defects, the acceptable quality limit (AQL) shall be 0%; for major defects, the AQL shall be 1%; for minor defects, the AQL shall be 4%.

1.2 Injectable

At the discretion of the Purchaser, part of the selected sample may be sent to a qualified government drug testing laboratory for physical, chemical or microbiological testing as follows.

Pharmacopoeial tests

- Active ingredient(s) identification and assay
- Appearance (colour, turbidity, visible particles)
- Filling volume
- pH
- Preservative identification
- Pyrogens
- Sterility

Non-pharmacopoeial tests

- Package seal integrity test
- Particle size (for suspensions only)

A Certificate of Analysis for production lot(s) represented by test samples shall be made available to the inspector and/or Purchaser upon request. The certificate shall state all tests performed, their specifications and actual test results obtained. All pharmacopoeial test results shall meet applicable pharmacopoeial limits.

1.3 Resolution of Defects

a. Packaging, Packing and Markings

Defects in exterior shipping carton markings must be corrected by the Supplier prior to shipment.

All goods from corresponding production lots with inspection lot defect in excess of the AQLs listed in Section 1.4 of this specification must be corrected and reinspected at Supplier's expense or rejected.

b. Injectable

Any deviation from the manufacturer's Certificate of Analysis, product specifications or relevant pharmacopoeial limits shall result in rejection of goods from the entire production lot.

Technical Specification - Male Latex Condom

(from WHO document "The Male Latex Condom.Specifications and Guidelines for Condom Procurement :2003")

1. General Requirements

Materials

a. The condoms shall be made of natural rubber latex.

b. The condoms shall not liberate toxic or otherwise harmful substances in amounts that can be irritating, sensitizing or otherwise harmful to the user of the condom under normal conditions of use.

c. Safety assessments shall be conducted in accordance with ISO 10993 or equivalent methods.

d. Manufacturers shall take steps to minimize the level of water-extractable proteins in the condoms.

e. A suitable dusting powder (e.g., cornstarch, magnesium and calcium carbonates) should be used to prevent the condoms from sticking together during manufacture and allow them to unroll easily. Talc or lycopodium spores shall not be used. Manufacturers should not use excess powder (maximum recommended is 50 mg per condom).

Shelf Life

a. Condoms shall comply with the performance requirements of this Technical Specification throughout the stated shelf life of the condom.

b. The manufacturer shall stipulate a shelf life based on the outcome of stability studies and measured from the date of manufacture. This shelf life shall be not less than three years and not more than five years.

c. Shelf life shall be confirmed by real time stability studies conducted at (30-2+5) °C according ISO 4074:2002, Section 7.3. If results from such studies are not available prior to the pre-qualification stage, manufacturers must initiate the studies immediately. Pending the outcome of the real-time studies, manufacturers may rely upon:

- Accelerated stability studies at elevated temperatures to estimate the shelf life of their products
- Their own established and validated procedures for establishing shelf life estimates

d. Advice on conducting and analysing stability studies is in ISO 4074:2002, Section 7.4, Annex K. Data from such studies should be reviewed as part of the pre-qualification procedure. If at any time during the real-time studies the manufacturer becomes aware that the shelf life estimates made using the accelerated studies are incorrect, the purchasers must be notified immediately.

Minimum Stability Requirements
Condoms shall comply with the minimum stability requirements defined in ISO 4074:2002, Section 7.2.

Sampling: Three LOTS sampled in accordance with ISO 2859-1, Inspection Level G-I but at least Code Letter M.

Conditioning: Incubate samples in their individual, sealed containers according to Annex H of ISO 4074:2002; one set for 168 ± 2 hours at 70 ± 2 °C and the other set for 90 ± 1 days at 50 ± 2 °C. At the end of the incubation periods, withdraw the condoms and test for airburst properties.

Testing: In accordance with test method in ISO 4074:2002, Annex G.

Requirement: Minimum bursting requirements:

- AQL 1.5
- Volume
  - -- 16.0 dm3 for condoms with widths less than 50.0 mm
  - -- 18.0 dm3 for condoms with widths 50.0 mm up to 56.0 mm
  - -- 22.0 dm3 for condoms with widths greater than 56.0 mm
- Pressure
  - -- 1.0 kPa (for all widths)

The width is defined as the mean lay flat width of 13 condoms measured in accordance with Annex E of ISO 4074: 2002 at a point (75 ± 5) mm from the closed end.

2. Performance Requirements

The performance requirements specified here are based on the requirements of ISO 4074:2002. These requirements cannot be altered. Verification of compliance with these requirements is to be done as part of pre-qualification and the LOT-by-LOT compliance testing of the product.

Bursting Volume and Pressure
Sampling: In accordance with ISO 2859-1, Inspection Level G-I.

Testing: In accordance with test method in ISO 4074:2002, Annex G, clauses 6.1 (before oven conditioning) and 6.2 (after oven conditioning) for (168 ± 2) hours at (70 ± 2) °C.

Requirement: Minimum bursting requirements:

- AQL 1.5
- Volume
  - -- 16.0 dm3 for condoms with widths less than 50.0 mm
  - -- 18.0 dm3 for condoms with widths 50.0 mm up to 56.0 mm

-- 22.0 dm3 for condoms with widths greater than 56.0 mm

- Pressure

-- 1.0 kPa (for all widths)

The width is defined as the mean lay flat width of 13 condoms measured in accordance with ISO 4074:2002, Annex E at a point (75 ± 5) mm from the closed end.

Freedom from Holes and Visible Defects
Sampling: In accordance with ISO 2859-1, Inspection Level G-I but at least Code Letter M.

Testing: In accordance with test method in ISO 4074:2002, Annex L.

- Freedom from holes: AQL 0.25
- Visible defects: AQL 0.4

There is a more detailed discussion on critical and non-critical visible defects in Section 1.

Package Integrity (seal integrity)
Sampling: In accordance with ISO 2859-1, Inspection Level S-3.

Testing: In accordance with test method in ISO 4074:2002, Annex M.

Requirement: AQL 2.5

3. Design Requirements

Shape and Texture
a. The surface of the condoms shall be non-textured throughout.

b. The recommended condom should have straight and parallel sides, without constrictions and with a visible shoulder leading to a reservoir tip.

c. Shape may be modified in line with normal commercial condom designs.

If the shape is other than above, attach a dimensioned drawing with detailed description andcheck here.

Verify above by visual inspection.

Integral Bead
The open end of the condom shall have a rolled ring of latex called an integral bead.

Colour

a. The recommended condom should be translucent and without added colouring.

If coloured condoms are desired, pigments must be suitable for use in medical devices.

If a pigment is required, indicate the colour here.

Verify above by visual inspection.

Scents and Flavouring

a. The condoms shall not give off an unpleasant odour when the package is opened at any time after manufacture and for the shelf life of the product. (Condoms have a characteristic odour of rubber, which tends to dissipate quickly once the package is opened.)

b. Appropriate reference samples should be retained by the testing laboratory and can be used to resolve disputes over odour.

c. The recommended condom should be free from added fragrance and flavouring agents.

d. Users may specify the addition of a suitable fragrance or flavour to mask the characteristic rubber odour. Such fragrances and flavours must be non-toxic and non-irritating and must not degrade the rubber as demonstrated by biocompatibility studies conducted according to ISO 10993.

If a fragrance is desired, describe here.

If a flavour is desired, describe here.

Verify by visual inspection and smell.

Width

Sampling: In accordance with ISO 2859-1, Inspection Level S-2.

Testing: In accordance with test method in ISO 4074:2002, Annex E.

Requirement: A width of 53 mm, with a tolerance of ± 2 mm is allowed for individual condoms with a tolerance of ± 1 mm for the mean of the LOT.

AQL 1.0

If the width is not (53 ± 2) mm, indicate the width here.

Length

Sampling: In accordance with ISO 2859-1, Inspection Level S-2.

Testing: In accordance with test method in ISO 4074:2002, Annex D.

Requirement: A minimum of 170 mm for condoms with widths less than 50.0 mm.

A minimum of 180 mm for condoms with widths of 50.0 mm up to 56.0 mm.

A minimum of 190 mm for condoms with widths greater than 56.0 mm.

AQL 1.0

Other lengths may be specified based on the best available data on the target population.

Thickness

Sampling: In accordance with ISO 2859-1, Inspection Level S-2.

Testing: In accordance with test method in ISO 4074:2002, Annex F.

Requirement: The thickness measurements are taken at three points: 30 ± 5 mm from the open end, 30 ± 5 mm from the closed end (excluding the reservoir tip), and at the mid-distance between those two points.

AQL 1.0

The mean single-wall thickness (calculated from the three individual measurements) for each condom shall be 0.065 ± 0.015 mm.

Quantity of Lubricant Including Powder

Sampling: In accordance with ISO 2859-1, Inspection Level S-2.

Testing: In accordance with test method in ISO 4074:2002, Annex C.

Requirement: The condom shall be lubricated with a quantity of silicone fluid having a viscosity between 200 and 350 centistokes.

Other lubricants such as glycols and water-based lubricants may be used. Oil-based lubricants should NOT be used.

If an alternative lubricant is required, specify the type here.

The quantity of lubricant, including powder, in the package should be 550 ± 150 mg.

AQL 4.0

If user preferences indicate that it is desirable, lower lubricant levels may be used, but the minimum recommended quantity is 250 mg.

If the lubricant quantity is less than 550 ± 150 mg, indicate here.

Individual Package Materials and Markings
Sampling: In accordance with ISO 2859, Inspection Level S-3.

Testing: The sample of condom packages is visually inspected to verify the required aspects of package quality.

Requirement: The colour, print design and identification markings, including Pantone references and font sizes, shall be as specified by the buyer and attached to this specification.

Individual packages shall be square and shall not distort the rolled condom. The package shall be hermetically sealed and shall protect the product from oxygen, ozone, water vapour, ultraviolet and visible light.

Verify by visual inspection.

The recommended packages should be constructed of a laminate, which includes a layer of suitable impermeable flexible aluminum foil (recommended minimum thickness of 8 micrometers), and layers of plastic materials suitable for the mechanical protection of the metal foil and for printing and sealing.

Alternative packaging materials can be accepted if their impermeability and strength are comparable to the recommended packaging above, or if there is real-time stability data to show the condom in its pack has adequate shelf-life.

If an alternative material is required, attach the full specification and mark here.

The LOT numbers on packages must be printed at the time of packaging.

Verify by Supplier's data or independent test.

In addition, the following shall apply:

- There shall be no evidence of leakage.
- The outside surface of the package shall be clean.
- There shall be no separation of the layers of laminate.
- If the sealed packages are in strips, the individual packages are separated by perforations or other means that allow the packages to be separated by hand without interfering with the seals.
- The package must be easy to open without damaging the condom.

Requirement: The individual package shall be individually marked as follows:

- Manufacturer's name
- LOT number of LOT identification code (printed at the time of packaging, not pre-printed)

- Manufacturing date (dip date): Month and year – labelled Manufacturing date
- Expiry date: Month and year – labelled expiry date
- Date in a language to be specified by the purchaser.

AQL 2.5

4. Packaging for Shipment

Inspections or verifications in this section will generally be carried out at the pre-qualification stage and during periodic audits.

Consumer Packs

a. No consumer packs are included in the specification. The purchaser should specify in accordance with the requirements of the programme.

Inner Boxes

a. The inner boxes shall be constructed of board plasticized on its inner surface and of sufficient strength and rigidity that the box will retain its shape through every stage of the distribution chain.

b. The inner boxes will be marked in a legible manner to show the contents and to facilitate identification in case of subsequent query.

The following information shall be included in the inner box marking:

- Lot identification number
- Month and year of manufacture (including the words Date of Manufacture, Month, Year) in language(s) to be specified by the purchaser. The year will be written as a four-digit number and the month as a two-digit number.
- Month and year of expiry (including the words Expiry Date, Month, Year) in language(s) to be specified by the purchaser. The year will be written as a four-digit number and the month as a two-digit number.
- Manufacturer's name and registered address
- Nominal width, expressed in millimeters
- Number of condoms in box
- Instructions for storage

Note: All markings must be legible. Can be specified in accordance with program requirements.

Exterior Shipping Cartons

a. The inner boxes shall be packed into plastic or other waterproof lining bags, which will be placed in three-walled corrugated fibreboard cartons made from weather-resistant fibreboard with a bursting test strength of not less than 1900 kPa.

b. The carton flaps shall be secured with water-resistant adhesive applied to not less than 75% of the area of contact between the flaps or with 75-mm-wide water-resistant tape applied to the full length of the centre seams and extending over the ends not less than 75 mm.

c. The cartons will be secured by plastic strapping at not less than two positions.

d. Alternatively, wire-bound, cleated plywood or nailed wood boxes are acceptable when lined with a waterproof barrier material. The barrier material must be sealed at the edges with waterproof tape or adhesive and there must be no sharp protrusions inside the boxes.

e. The exterior shipping carton, like the inner box, shall be marked with information about the contents in a clearly legible manner. The information shall include:

- LOT identification number
- Month and year of manufacture (including the words Date of Manufacture, Month, Year) in language(s) to be specified by the purchaser. The year shall be written as a four-digit number and the month as a two-digit number.
- Month and year of expiry (including the words Expiry Date, Month, Year) in language(s) to be specified by the purchaser. The year shall be written as a four-digit number and the month as a two-digit number.
- Name and address of supplier
- Nominal width
- Number contained in the carton
- Instructions for storage and handling

LOT Traceability

a. To facilitate monitoring of LOT quality during shipping and storage, all exterior shipping cartons for each discrete LOT shall be assembled and shipped together.

b. Best efforts shall be made to ensure that shipments remain as discrete LOTS and that these LOTS remain intact as far down the distribution system as possible.

c. These efforts may include the use of very large lettering for LOT codes on the exterior shipping cartons, colour coding and palleting of discrete LOTS. Instructions to this effect shall be issued to shipping and warehouse personnel.

5. Registration and Certification Requirements

Certificate of Registration Status in Country of Origin
Condoms offered under this purchase description shall be licensed for marketing by the drug regulatory authority of the country of origin. Prior to award of the Contract, the successful offeror(s) may be required to submit a "statement of licensing status of pharmaceutical products(s)" as provided under the World Health Organization (WHO) Certification Scheme.

Compliance with Good Manufacturing Practices
The Supplier must be able to provide certification that the oral contraceptives are manufactured according to WHO good manufacturing practices (GMP). Such certification can be found in the WHO Certification Scheme "Certificate of a Pharmaceutical Product". Supplier also must be able to provide copies of its annual GMP audit reports.

6. Quality Assurance Provisions

Compliance
The Supplier shall guarantee that the products as packed for shipment comply with all provisions of the specification and related documents.

Documentation
The Supplier shall provide evidence of the satisfaction of the technical specification requirements for which specific inspection instructions or protocols have not been provided. Such evidence is contained in the "Manufacturer's Batch Certificate" under the WHO Certification Scheme.

The Supplier shall provide a copy of the manufacturing record and procedures to the Purchaser for each lot intended for shipment.

The Supplier shall provide a copy of the Certificate of Analysis to the Purchaser for each lot intended for shipment.

The Supplier shall provide to the Purchaser a copy of the approval of each component for each lot intended for shipment.

Inspection by the Purchaser
The Purchaser reserves the right to perform or cause to be performed any of the inspections and tests set forth in the Specification and Special Conditions of Contract to ensure that the contraceptives conform to prescribed requirements.

The Purchaser reserves the right, and/or may assign the right to a representative, to enter and inspect the production facility prior to shipment of the contraceptives and

to draw samples from the Supplier's factory and/or warehouse. Except as otherwise specified in the contract or purchase order, prior to shipment the Purchaser will sample or cause to be sampled the product as packed in inner boxes preparatory to packing in exterior shipping cartons. The sampling shall be according to recognized standards.

The Purchaser may have some or all of the tests specified in the Technical Specification performed by a laboratory suitably equipped and qualified to conduct quality assurance tests on condoms according to WHO requirements.

Technical Specification: TCu380A Intrauterine Device (IUD)

(From WHO draft TCU380A IUD Specification Document May 2010)

1. General Description

The TCu380A IUD consists of a T shaped frame made from low density polyethylene with barium sulphate added for x-ray opacity. The device is 32 mm wide and 36 mm long with a plastic ball at the bottom of the vertical stem to guard against cervical penetration. A small hole may be located on the vertical stem near to its junction with the horizontal arms to act as an anchor for the copper wire. The IUD has solid copper collars on each of its two horizontal arms, each of which has a surface area of 35 mm2 and copper wire of 310 mm2 surface area wound tightly around the vertical stem, giving a total surface area of 380 mm2, as indicated in the name of the device A pigmented polyethylene filament is tied in a knot through a small hole in the ball to provide two equal length threads, as a means to locate and remove the device.

The device is supplied sterile in a sealed primary pack together with an insertion instrument consisting of a high-density polyethylene tube and a rod to hold the device correctly positioned within the uterus while the introducer is removed. A moveable plastic flange is positioned on the insertion tube to control the depth of insertion to locate the IUD correctly within the uterus during insertion.

It is recommended that all biological safety in accordance with ISO 10993 parts 1, 3, 5, 10 and 11 is conducted by accredited laboratories.

2. Materials

The following materials shall be used.

2.1 T frame

The T Frame shall be made from low density polyethylene (LDPE) free of stabilizers having a minimum tensile strength of 13 MPa (ASTM D638 − ISO 527−2, using a crosshead speed of 50 mm/min and a type 1 specimen bar) and a 2% secant flexural modulus in the range 133.5 MPa to 180.6 MPa (ASTM D790).

The LDPE shall be blended with 15% to 24% USP precipitated barium sulphate with a particle size of 95% less than 10 micron. The compounded polymer (LDPE plus barium sulphate) shall be evaluated for biological safety in accordance with ISO 10993-1 requirements for mucosal membrane contact devices intended for permanent contact. Specifically the following testing is required:

- Testing for genotoxicity according to ISO 10993-3
- Testing for cytotoxicity testing according to ISO 10993-5

- Testing for irritation and delayed-type hypersensitivity according to ISO 10993-10
- Testing for subacute and subchronic toxicity according to ISO 10993-11

For a specific material, it is only necessary to carry out the assessment of biological safety once. The evaluation shall be repeated if there is a significant change to the materials, for example, if the grade or supplier is changed.

It has been agreed that manufacturers using the original grade of LDPE specified by the Population Council may continue to use this material for a period of two years from the date of publication of this specification before completing this testing.

2.2 Copper wire

The wire shall be made from Oxygen Free Electronic (OFE) 99.99% pure copper meeting the National Bureau of Standards designation UNS C10100. The diameter of the wire shall be (0.255 ± 0.005) mm (30 AWG[1], 33 ISWG[2]).

2.3 Copper collars

The copper collars shall be made from Oxygen Free Electronic (OFE), 99.99% pure copper meeting the National Bureau of Standards designation UNS C10100[3]. The collars shall be manufactured from copper tube half hard temper with internal diameter (1.68 ± 0.025) mm and external diameter: (2.2 ± 0.025) mm. The collars shall be (5 ± 0.15) mm in length.

The collars shall be deburred, polished and free from sharp edges, for example by barrel tumbling.

2.4 Thread

The thread shall be monofilament made from high density polyethylene, (HDPE) free of stabilizers having a sufficient minimum tensile strength to produce a thread meeting the specified strength requirement (9.5 Newton). A material with a minimum tensile strength (ASTM D6380, ISO 527-2) of 28 MPa is recommended.

The thread polymer shall be compounded with 0.4% up to 1.0% by weight of USP (EP) rutile titanium dioxide.

[1] American Wire Gauge

[2] Imperial Standard Wire Gauge

[3] See Annex 3 Summary Specification for Copper Purity

The compounded polymer (HDPE plus titanium dioxide) shall be evaluated for biological safety in accordance with ISO 10993-1 requirements for mucosal membrane contact devices intended for permanent contact. Specifically the following testing is required:

- Testing for genotoxicity according to ISO 10993-3
- Testing for cytotoxicity testing according to ISO 10993-5
- Testing for irritation and delayed-type hypersensitivity according to ISO 10993-10
- Testing for subacute and subchronic toxicity according to ISO 10993-11

For a specific material, it is only necessary to carry out the assessment of biological safety once. The evaluation shall be repeated if there is a significant change to the materials, for example, if the grade or supplier is changed.

Manufacturers using the original grade of HDPE specified by the Population Council or an equivalent grade that has been used for more than 5 years may continue to use the current material for a period of two years from the date of publication of this specification before completing this testing.

The thread diameter shall be (0.25 ± 0.05) mm. When tested according to ISO 7439: 2002 clause 7 (clamping the thread only) the peak load at break of the thread shall be greater than 9.5 Newton.

2.5 Insertion tube

HDPE (High Density Polyethylene) Food Contact grade of internal diameter (3.7 ± 0.1) mm and outside diameter of (4.4 ± 0.1) mm.

2.6 Insertion rod

Food contact grade radiation stable ABS (Acrylonitrile-Butadiene-Styrene polymer) or food contact grade radiation stabilized polypropylene (PP) with a tip diameter of (2.6 ± 0.2) mm.

Optionally the insertion rod may be pigmented.

2.7 Positioning flange

Polymer with adequate radiation stability to function mechanically post-sterilization. Optionally the flange may be pigmented.

2.8 Packaging

Packaging materials shall comply with ISO 11607-1.

Polymer films shall be used, preferably continuous, to reduce the risk of tarnishing the copper.

Tarnishing is a natural phenomenon for copper and does not affect the performance of the IUD. However, significant tarnishing of copper during shelf life may not be aesthetically acceptable. The use of continuous film packaging, where possible, can reduce the risk of tarnishing

3. Materials Testing

Every new batch (lot) of compounded frame material (LDPE plus barium sulphate) and thread material (HDPE plus titanium dioxide) shall be subjected to *in vitro* cytotoxicity testing in accordance with ISO 10993 – 5 (Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity).

The cytotoxic response shall not be worse than that recorded for the compounded material when originally evaluated for biological safety according to the requirements of ISO 10993-1.

The barium sulphate content of the frame material shall be determined according to ISO 7439: 2002 clause 7.5.

4. Materials Storage

The recycling of injection moulded reclaim material for the T frame and the thread is not permitted.

6. Dimensions and Requirements for Finished Product

When tested according to ISO 7439: 2002 clause 7.2, the dimensions of the finished product after sterilization shall comply with the requirements as individually specified below.

Sampling shall be in accordance with ISO 2859-1, Inspection Level S-4 unless otherwise indicated. Compliance shall be with an AQL of 0.65 unless otherwise indicated.

Manufactures and testing laboratories may opt to sample in accordance with ISO 3951-1 using the same Inspection level and AQL. In cases of dispute sampling according to ISO 2859-1 shall be used.

In order to use the tables in ISO 2859-1 it is necessary for the manufacturer to specify the batch (lot) size.

The manufacturer is responsible for defining the batch size (lot) and ensuring traceability and the use of appropriate sampling in process and product validation.

6.1 T frame dimensions

Length of horizontal arms (total length of both arms): (32 ± 0.5) mm

Length of vertical stem: (36 ± 0.5) mm

Diameter of horizontal arm: (1.6 ± 0.1) mm

Diameter of vertical stem: (1.5 ± 0.1) mm

Optionally a hole for anchoring an end of the copper wire may be provided. The hole must not reduce the breaking strength of the vertical stem that is specified below in Performance Requirements 7.4.

6.3 Breaking strength

The hole may be tapered or dumbbell shaped with a maximum diameter: 0.55 mm and placed (2.8 ± 0.14) mm from the intersection of the horizontal arm and vertical stem centrelines.

T Piece Ball (at end of vertical stem) diameter: (3.0 mm ± 0.7 mm). The junction between the ball and the vertical stem shall preferably be radiused.

T Piece Ball (at end of vertical stem) shall have a hole of maximum diameter 0.79 mm for securing the thread. The hole may be tapered or dumbbell shaped.

The junctions between the horizontal arms and the vertical stem may be radiused to prevent stress concentrations. If the junction is radiused the radius shall be between 0.25 – 0.40 mm. Manufacturers shall confirm that introducing the radius does not lead to an increase in crush damage at the junction when the T is deformed as it is loaded into the insertion tube. This can be done by comparing the strength of radiussed and non radiused T frames after loading in the insertion tube. Microscopic examination should be used alongside strength testing to monitor the extent of any damage.

6.3 Thread dimension

Sampling shall be in accordance with ISO 2859-1, Inspection Level S-4. Manufactures and testing laboratories may opt to sample in accordance with ISO 3951-1 using the same Inspection level and AQL. In cases of dispute sampling according to ISO 2859-1 shall be used.

Compliance shall be with an AQL 1.5 for thread length.

Thread Length: The length of each tail shall be 105 to 125 mm.

6.4 Copper collars

Collar length: (5.0 ± 0.15) mm

Collar weight: (68.7 ± 3.0) mg

Collar Position: 5.4 ± 0.4 mm from the ends of the T horizontal arm.

6.5 Copper wire
The weight of wire on the frame shall be not less than 165 mg and not more than 187 mg.

6.6 Insertion tube
Length: (206 ± 2) mm

Internal Diameter: (3.7 ± 0.1) mm
Outside Diameter: (4.4 ± 0.1) mm

6.7 Insertion rod
Length: (190 ± 5) mm from handle brace to tip.
Diameter at tip: (2.6 ± 0.2) mm

6.8 Insertion tube flange
Sampling shall be in accordance with ISO 2859-1, Inspection Level S-4. Manufactures and testing laboratories may opt to sample in accordance with ISO 3951-1 using the same Inspection level and AQL. In cases of dispute, sampling according to ISO 2859-1 shall be used.

Compliance shall be with an AQL of 1.5.

Diameter of central hole: (4.1 ± 0.1) mm

The shape and dimensions of the central hole may be changed to facilitate meeting the specified flange displacement force.

6.9 Other assist components
These are other optional components which the manufacturer may evaluate and choose to include. When considering design and choice of materials for these components, manufacturers shall take into account the function of the devices, the type and duration of exposure to the body and the effect of sterilization by gamma radiation.

7. Performance Requirements

7.1 Copper surface area
The total nominal active copper surface area, wire and collars shall be 380 mm2 ± 10%.

7.2 Copper wire winding
The wire shall be wound so that it is in contact with the frame and is uniform. The proximal and distal end of the wire must lie smoothly on the T surface and not protrude beyond the wire profile to prevent any chance abrasion of uterine tissue during insertion or *in situ.*

The length of wire protruding from the anchoring hole (‘the tag’) shall not exceed 10mm. It shall be bent down to run parallel with the vertical stem and not interfere with the position of the arms when the IUD is placed in the insertion device.

Single and double wound configurations are acceptable.

7.3 Thread knot

The knot shall be secure and not promote breakage under normal use.

7.4 Breaking strength

Sampling shall be in accordance with ISO 2859-1, Inspection Level G I. Manufactures and testing laboratories may opt to sample in accordance with ISO 3951-1 using the same Inspection level and AQL. In cases of dispute, sampling according to ISO 2859-1 shall be used.

Compliance shall be with an AQL of 1.0.

When pulled at 200 mm/minute, according to ISO 7439: 2002 clause 7.3 with the arms bent upwards and clamped parallel (8 ± 2) mm and a single thread clamped, the breaking force of the finished product after sterilization shall be greater than 9.5 Newton.

Temperature during testing shall be 23± 2C°.

Conditioning as specified in ISO 7439: 2002 needs to be carried out only in the case of disputes.

When conducting the tensile test, the T frame shall be clamped by the copper collars (only) on the horizontal arms, using a gripping fixture that deforms the arms simultaneously parallel to each other and to the vertical stem, with horizontal arms (8 ± 2) mm apart, centre-line to centre-line. The tee junction must be unconstrained by the clamp.

In use, the toggle clamp should be sufficiently tightened to prevent slippage but not so tight that it fully crushes the collars.

One of the threads shall be gripped in the opposing grip at a distance of 5 cm from its point of attachment to the IUD. A grip with parallel flat rubber faces has been found satisfactory if well-tightened. Force is then applied and the IUD is stretched until either it or the thread breaks or detaches. The force at break or detachment is measured and recorded. Any tensile test should be rejected if breakage of the thread occurs at the entry to the grip.

The location of failure for any device failing the minimum strength requirement shall be noted (thread, thread/ball junction, wire insertion hole in vertical stem, or the junction between the vertical and horizontal arms).

7.5. Flexibility test

Sampling shall be in accordance with ISO 2859-1, Special Inspection Level S-4. Manufactures and testing laboratories may opt to sample in accordance with ISO 3951-1 using the same Inspection level and AQL. In cases of dispute sampling according to ISO 2859-1 shall be used.

Compliance shall be with an AQL of 4.0.

When a 20g weight is applied to one of the horizontal arms of the T frame for a period of 20 seconds at a distance 12 mm from the vertical arm, the deflection of the horizontal arm measured at the end of the arm shall be as follows:

For freshly manufactured T frames that are greater than 24 hours but less than 96 hours from time of moulding: within the range 4.8 mm to 6.5 mm.

For T frames that are older than 96 hours: greater than 4.0 mm.

The test shall be carried out at a temperature of (23 ± 2) °C. Before testing the T frames shall be stored for at last 6 hours at the test temperature.

A suitable test rig may be used to clamp the T frame and measure the amplitude of the defection. A pivoted needle or lever may be used to amplify the deflection of the horizontal arm Flexibility Apparatus. If such a test rig is used the T frame arm deflection may be converted into a scale reading using the appropriate amplification factor for the rig.

7.6 Copper collar retention force

Sampling shall be in accordance with ISO 2859-1, Inspection Level S-4. Manufactures and testing laboratories may opt to sample in accordance with ISO 3951-1, using the same Inspection level and AQL. In cases of dispute sampling according to ISO 2859-1 shall be used.

Compliance shall be with an AQL of 4.0.

The minimum force required to displace a collar on the arm shall be 6.86 Newton (700 g -force).

When conducting the copper collar retention force, test the T frame shall be clamped by the collar on one of the arms using a suitable jig if necessary and the opposing arm shall be gripped in the opposite clamp.

Optionally one collar may be clamped in one jaw and the other collar clamped in the opposing jaw. The clamp(s) gripping the copper collar shall have a groove milled with a 1.59 mm (1/16 inch) ball end mill to a depth of 1.38 mm, or about 65% of the collar diameter, to prevent crushing the collar.

7.7 Memory

When the finished product after sterilization is tested according to ISO 7439: 2002 clause 7.4, the maximum displacement from the horizontal of the horizontal arms shall be not greater than 5.0 mm.

Sampling shall be 20 units per lot irrespective of lot size.

7.8 Insertion instrument

The insertion rod shall be a snug fit but slide smoothly within the insertion tube and shall not trap the thread.

7.9 Flange displacement force
Sampling shall be in accordance with ISO 2859-1, Inspection Level S-4. Manufactures and testing laboratories may opt to sample in accordance with ISO 3951-1 using the same Inspection level and AQL. In cases of dispute, sampling according to ISO 2859-1 shall be used.

Compliance shall be with an AQL of 0.65.

Use a steadily applied displacement. The required force should fall between 2.0 and 9.0 Newton.

8. Packaging

Packaging shall comply with ISO 11607 Part 1.

Continuous polymer films shall be used to reduce the risk of tarnishing unless ethylene oxide is used for sterilization.

Continuous polymer films cannot be used with ethylene oxide sterilization. A suitable Ethylene Oxide permeable microbiological barrier shall be used in accordance with ISO 11607 Part 1.

8.1 Sealed pouch
IUDs shall be packed in individual sealed pouches.

8.2 Sealed pouch integrity
Sampling shall be in accordance with ISO 2859-1, Inspection Level S-4.

Compliance shall be an AQL of 0.65.

Sealed pouch integrity shall be tested according to ASTM D3078 (Standard test method for determination of leaks in flexible packaging by bubble emission).

If permeable packaging material is used, sealed pouch integrity shall tested by ASTM F 1929 (Standard test method for detecting seal leaks in porous medical packaging by dye penetration).

8.3 Sealed pouch peel strength
Sampling shall be in accordance with ISO 2859-1, Inspection Level S-4. Manufactures and testing laboratories may opt to sample in accordance with ISO 3951-1, using the same Inspection level and AQL. In cases of dispute sampling according to ISO 2859-1 shall be used.

Compliance shall be with an AQL of 0.65

When tested according to ASTM F 88 (standard test method for seal strength of flexible barrier materials) the peel force shall be not less than 4.4 N/2.54 cm and not greater than 19 N/2.54 cm.

- If the packaging is made from two equally flexible materials Technique B of ASTM F 88 shall be used (sample supported at 90^0 by hand).
- If a rigid material is used as part of the pack, for example a moulded tray then Technique C of ASTM F 88 shall be used (sample supported at 180^0).

8.4 Labelling and inserts
Information required in accordance with ISO 7439 including information intended for the women shall be provided in accordance with the contractual requirements agreed with the purchaser. Up-to-date information on IUDs can be obtained from WHO publications already referenced in this document.

The following information shall be supplied:

The Latest Insertion Date (LID) is the date after which the product cannot be inserted in utero.

The Latest Insertion Date shall be printed on the sealed pouch and shall be based on the maximum product shelf life from the date of sterilization.

The sterilization shall be completed within 30 days of sealing the finished device in the pouch.

In addition, the duration of the maximum period the device can remain in utero shall be printed on the primary container. This period shall not exceed 12 years from the date of insertion.

8.5 Printing
All printing shall be clear and readily legible.

8.6 Cleanliness
The device, insertion tube, insertion rod, flange and any insert such as instructions included in the pack shall be free of visible particulate matter.

9. Sterility

9.1 Sterilization method
Sterilization shall be by radiation according to ISO 11137 series or by Ethylene Oxide according to ISO 11135 series and standards normatively referenced therein. Radiation sterilization is preferred to allow the use of continuous polymer film packaging materials.

9.2 Sterility assurance level
The sterilization assurance level shall be 10-6.

9.3 Residual Ethylene Oxide levels
If ethylene oxide sterilization is used, then residual ethylene oxide levels shall not exceed 10 ppm and ethylene chlorohydrin levels shall not exceed 20 ppm on any individual sample when measured using a method that complies with the requirements of ISO 10993-7.

Average residual levels across all samples tested shall not exceed 5 ppm for ethylene oxide and 10 ppm for ethylene chlorohydrin.

10. Latest insertion date (LID)

The maximum permitted shelf life for storage of the device prior to insertion is 5 years and this defines the 'Latest Insertion Date ' (LID).

A two year transition period from the date of publication of the specification to implement this requirement has been agreed with the manufacturers.

Shelf life claims shall be supported by appropriate stability data.

Guidance on conducting stability studies is given in Annex 5 – Accelerated Ageing Testing.

When conducting stability studies, manufacturers shall include products assembled from components that have been stored for the maximum component storage periods, specified by the manufacturer.

11. Materials Procurement - Good Manufacturing Practice (GMP)

Manufacturers shall take appropriate steps to ensure that batches of compounded materials (T and thread materials) are not contaminated by any extraneous impurities during compounding operations.

Where lubricants are used in moulding, the grades shall be 'Food Grade' and/ or suitable for medical device manufacture. Manufacturers shall introduce procedures to monitor and control the degree of tarnish and rough edges on the copper component. If appropriate the copper components should be cleaned prior to assembly.

12. Dimensional Tolerances and Manufacturing Tolerance Specifications

The nominal specified dimensions and tolerances may not provide the correct clearance for components such as the insertion rod which must slide smoothly and the flange which has to have the correct displacement force. It remains the responsibility of the manufacturer to produce a fully functioning, safe and effective product within the dimensional tolerance limits provided.

13. Workmanship

Finished IUDs should be inspected visually for evidence of visible defects and poor workmanship. Defects are divided into two categories depending upon the level of impact they may have on the safety, effectiveness and acceptability of the product. Defects that might be expected to affect the safety and or effectiveness of the product are classified as critical defects and an AQL of 0.65 is applied. Defects that might affect the acceptability of the product, causing the device to be rejected at the time of insertion, are classified as minor defects and an AQL of 2.5 applies. Manufacturers and testing laboratories should maintain

a list of these defects with clear definitions and diagrams or photographs to assist both in the assessment of workmanship and in the resolution of any disputes.

14. Critical Visible defects

0.65 AQL – assessed by visual examination not measurement

a) Tarnishing

b) Missing components

c) Flash on the mould lines of the T Frame

d) Sharp protruding edges and burrs

e) Unsecured thread

f) Incomplete/deformed ball

g) Deformed collars

h) Improperly sealed pouches

i) Empty pouches

j) Embedded/surface/foreign particles

Non-critical visible defects

2.5 AQL– all assessed by visual examination not measurement

a) Insertion rod bent or distorted
b) Discoloration of plungers
c) Damaged packing cartons – depending on severity

15. Certificate of Registration Status in Country of Origin

IUDs offered under this purchase description shall be licensed for marketing by the drug regulatory authority of the country of origin. Prior to award of the Contract, the successful offeror(s) may be required to submit a "statement of licensing status of pharmaceutical products(s)" as provided under the World Health Organization (WHO) Certification Scheme, if applicable.

16. Compliance With Good Manufacturing Practices

The Supplier must be able to provide certification that the IUDs are manufactured according to WHO good manufacturing practices (GMP). Supplier also must be able to provide copies of its annual GMP audit reports.

17. Quality Assurance Provisions

17.1 Compliance

The Supplier shall guarantee that the products as packed for shipment comply with all provisions of the specification and related documents.

17.2 Documentation

The Supplier shall provide evidence of the satisfaction of the technical specification requirements for which specific inspection instructions or protocols have not been provided. Such evidence is contained in the "Manufacturer's Batch Certificate" under the WHO Certification Scheme.

The Supplier shall provide a copy of the manufacturing record and procedures to the Purchaser for each lot intended for shipment.

The Supplier shall provide a copy of the Certificate of Analysis to the Purchaser for each lot intended for shipment.

The Supplier shall provide to the Purchaser a copy of the approval of each component for each lot intended for shipment.

17.3 Inspection by the Purchaser

The Purchaser reserves the right to perform or cause to be performed any of the inspections and tests set forth in the Specification and Special Conditions of Contract to ensure that the contraceptives conform to prescribed requirements. The Purchaser reserves the right, and/or may assign the right to a representative, to enter and inspect the production facility prior to supply of the contraceptives and to draw samples from the Supplier's factory and/or warehouse. Except as otherwise specified in the contract or purchase order, prior to shipment the Purchaser will sample or cause to be sampled the product as packed in inner boxes preparatory to packing in exterior shipping cartons. The sampling shall be according to recognized standards.

The Purchaser may have some or all of the tests specified in ..... the contract performed by a laboratory suitably equipped and qualified to conduct quality assurance tests on IUDs.

17.4 Sampling Procedures

The Purchaser or the Purchaser's representative shall select the required samples from the lot according to the Technical specification ..... of the Special Conditions of Contract. If the order is to be filled using more than one production lot, each production lot shall be separately sampled and tested.

Where an inspection lot is smaller that 10,001 units, it will be deemed to be 10,001 for determination of sample sizes. The normal, tightened, and reduced inspection provisions of ISO 2859 (Inspec).

Sample Forms

The following sample forms should be included in the bidding documents package as required by the specific procurement activity being conducted:

- Bid Submission Form
- Price Schedule for Contraceptives Manufactured outside of Pakistan
- Price Schedule for Domestic Contraceptives Manufactured within Pakistan
- Manufacturer's Authorization
- Bid Security Form (Bank Guarantee)
- Bid Security (Bid Bond)
- Form of Contract Agreement
- Performance Security Bank Guarantee
- Bank Guarantee Form for Advance Payment
- Certificate of a Pharmaceutical Product

Bid Submission Form

Date: [insert: date of bid]

IFB Number: [Purchaser specify: "IFB No.]

Contract: [insert: name of Contract]

To: *[Purchaser insert: Name and address of Purchaser]*

Dear Sir or Madam:

Having examined the Bidding Documents, including Addenda Nos. [insert numbers], the receipt of which is hereby acknowledged, we, the undersigned, offer to supply and deliver the contraceptives under the above-named Contract in full conformity with the said Bidding Documents for the sum of:

	[insert: amount of local currency in words]	*([insert: amount of local currency in figures])*
plus	*[insert: amount of foreign currency A in words]*	*([insert: amount of foreign currency A in figures])*
[as appropriate, include the following]		
plus	*[insert: amount of foreign currency B in words]*	*([insert: amount of foreign currency B in figures])*
plus	*[insert: amount of foreign currency C in words]*	*([insert: amount of foreign currency C in figures])*

(hereinafter called "the Total Bid Price") or such other sums as may be determined in accordance with the terms and conditions of the Contract. The above amounts are in accordance with the Price Schedules attached herewith and are made part of this bid.

We undertake, if our bid is accepted, to deliver the contraceptives in accordance with the delivery schedule specified in the Schedule of Requirements.

If our bid is accepted, we undertake to provide an advance payment security and a performance security in the form, in the amounts and within the times specified in the Bidding Documents.

We agree to abide by this bid, for the Bid Validity Period specified in Clause 18.1 of the Bid Data Sheet and it shall remain binding upon us and may be accepted by you at any time before the expiration of that period.

Until the formal final Contract is prepared and executed between us, this bid, together with your written acceptance of the bid and your notification of award, shall constitute a binding Contract between us. We understand that you are not bound to accept the lowest or any bid you may receive.

Commissions or gratuities, if any, paid or to be paid by us to agents relating to this bid, and to contract execution if we are awarded the Contract, are listed below:

Name and Address of Agent .....

.....

.....

Amount and Currency .....

Purpose of Commission or Gratuity .....

.....

(if none, state "none")

Dated this *[insert: number]* day of *[insert: month], [insert: year].*

Signed: .....

Date: .....

In the capacity of: ..... *[insert: title or position]*

Duly authorized to sign this bid for and on behalf of:

..... *[insert: name of Bidder]*

Price Schedule for Contraceptives Manufactured Outside of Pakistan

(Group C bids)

Name of Bidder _____. IFB Number __. Page _____ of ___.

1 Product code	2 Product	3 Strength	4 Dosage form	5 Unit pack size	6 Qty. offered	7 Unit prices				8 Total unit price [a+c+d] or [b+c+d]	9 Total price per item [6 x 8]	10 Local agent's commission as a % of FOB price included in quoted price	11 Shipment weight and volume	12 Name of manufac-turer-	13 Ctry. of origin	14 Pharma-copoeial standard
						[a] Unit price FOB or FCA port or place of loading	[b] CIF at port of entry or CIP named place of destina-tion (specify one)	[c] Inland transp., insurance & other local costs incidental to delivery if specified	[d] Other incidental costs as defined in the SCC							

Note:

(i) Column 7[c] is optional and it will be applicable only when required in accordance with ITB Sub-Clause 16.2 (b) (iv) and (v) and the related provisions in the Bid Data Sheet.

(ii) For column 9, pursuant to ITB 30.1, in the case of discrepancy between unit price and total price, the unit price shall prevail.

Total Bid Price:
Currency:
In figures:
In words:

Signed: _____

Dated: _____

In the capacity of: *[insert: title or other appropriate designation]*

Price Schedule for Domestic Contraceptives Manufactured within Pakistan

Name of Bidder _____. IFB Number _____. Page _____ of ___.

1 Product code	2 Product	3 Strength	4 Dosage form	5 Unit pack size	6 Qty. offered	7 Unit prices			8 Total unit price [a+b+c]	9 Total price per item [6 x 8]	10 Sales and other taxes payable if contract is awarded	11 Name of manufacturer	12 Pharma-copoeial standard	13 Local input in the cost as % of ex-factory price in column 7[a]
						[a] Ex-factory Ex-warehouse Ex-showroom Off the shelf	[b] Inland transp., insurance & other local costs incidental to delivery	[c] Other incident-al costs as defined in the SCC						

Note:

(i) Column 7[b] is optional and it will be applicable only when required in accordance with ITB Sub-Clause 16.2 (a) (iii) and (iv) and the related provisions in the Bid Data Sheet.

(ii) For column 9, pursuant to ITB 30.1 in the case of discrepancy between unit price and total price, the unit price shall prevail.

(iii) For column 13, a breakdown of the cost of local labour, local raw materials, and local components provided from within the country should also be indicated separately as specified in ITB Sub-Clause 27.1 along with adequate proof to substantiate each of these local inputs.

Total Bid Price:
Currency:
In figures:
In words:

Signed: _____

Dated: _____

Notes on Manufacturer's Authorization Form

The Bidder shall require the Manufacturer to fill in this Form in accordance with the instructions indicated. This letter of authorization should be on the letterhead of the Manufacturer and should be signed by a person with the proper authority to sign documents that are binding on the Manufacturer. The Bidder shall include it in its bid, if so indicated in the BDS.

Manufacturer's Authorization

Date: *[insert: date (as day, month and year) of Bid Submission]*

ICB No.: *[insert: number of bidding process]*

To: *[insert: complete name of Purchaser]*

WHEREAS

We *[insert: complete name of Manufacturer],* who are official manufacturers of *[insert: type of contraceptives manufactured],* having factories at *[insert: full address of Manufacturer's factories],* do hereby authorize *[insert: complete name of Bidder]* to submit a bid the purpose of which is to provide the following contraceptives, manufactured by us *[insert: name and or brief description of the contraceptives],* and to subsequently negotiate and sign the Contract.

We hereby extend our full guarantee and warranty in accordance with Clause 27 of the General Conditions of Contract, with respect to the contraceptives offered by the above firm.

Signed: *[insert: signature(s) of authorized representative(s) of the Manufacturer]*

Name: *[insert: complete name(s) of authorized representative(s) of the Manufacturer]*

Title: *[insert: title]*

Duly authorized to sign this Authorization on behalf of: *[insert: complete name of Bidder]*

Dated on ..... day of ....., ... *[insert: date of signing]*

Bid Security Form (Bank Guarantee)

[The Bank shall fill in this Bank Guarantee Form in accordance with the instructions indicated.]

.....

[insert Bank's Name, and Address of Issuing Branch or Office]

Beneficiary: .....

.....

[insert Name and Address of Purchaser]

Date: .....

BID GUARANTEE No.: .....

We have been informed that *[insert name of the Bidder]* (hereinafter called "the Bidder") has submitted to you its bid dated (hereinafter called "the Bid") for the execution of *[insert name of contract]* under Invitation for Bids No. *[insert IFB number]* ("the IFB").

Furthermore, we understand that, according to your conditions, bids must be supported by a bid guarantee.

At the request of the Bidder, we *[insert name of Bank]* hereby irrevocably undertake to pay you any sum or sums not exceeding in total an amount of *[insert amount in figures]* (*[insert amount in words]*) upon receipt by us of your first demand in writing accompanied by a written statement stating that the Bidder is in breach of its obligation(s) under the bid conditions, because the Bidder:

(a) has withdrawn its Bid during the period of bid validity specified by the Bidder in the Form of Bid; or

(b) having been notified of the acceptance of its Bid by the Purchaser during the period of bid validity, (i) fails or refuses to execute the Contract Form, if required, or (ii) fails or refuses to furnish the performance security, in accordance with the Instructions to Bidders.

This guarantee will expire: (a) if the Bidder is the successful bidder, upon our receipt of copies of the contract signed by the Bidder and the performance security issued to you upon the instruction of the Bidder; or (b) if the Bidder is not the successful bidder, upon the earlier of (i) our receipt of a copy of your notification to the Bidder of the name of the successful bidder; or (ii) twenty-eight days after the expiration of the Bidder's Bid.

Consequently, any demand for payment under this guarantee must be received by us at the office on or before that date.

This guarantee is subject to the Uniform Rules for Demand Guarantees, ICC Publication No. 458.

.....

[signature(s)]

Bid Security (Bid Bond)

[The Surety shall fill in this Bid Bond Form in accordance with the instructions indicated.]

BOND NO. .....

BY THIS BOND *[insert name of Bidder]* as Principal (hereinafter called "the Principal"), and *[insert name, legal title, and address of surety],* authorized to transact business in *[insert name of country of Purchaser],* as Surety (hereinafter called "the Surety"), are held and firmly bound unto *[insert name of Purchaser]* as Obligee (hereinafter called "the Purchaser") in the sum of *[insert amount of Bond]*[1] *[insert amount in words],* for the payment of which sum, well and truly to be made, we, the said Principal and Surety, bind ourselves, our successors and assigns, jointly and severally, firmly by these presents.

WHEREAS the Principal has submitted a written Bid to the Purchaser dated the ..... day of ..... , 20 ..... , for the construction of *[name of Contract]* (hereinafter called the "Bid").

NOW, THEREFORE, THE CONDITION OF THIS OBLIGATION is such that if the Principal:

withdraws its Bid during the period of bid validity specified in the Form of Bid; or

having been notified of the acceptance of its Bid by the Purchaser during the period of Bid validity; (i) fails or refuses to execute the Contract Form, if required; or (ii) fails or refuses to furnish the Performance Security in accordance with the Instructions to Bidders;

then the Surety undertakes to immediately pay to the Purchaser up to the above amount upon receipt of the Purchaser's first written demand, without the Purchaser having to substantiate its demand, provided that in its demand the Purchaser shall state that the demand arises from the occurrence of any of the above events, specifying which event(s) has occurred.

The Surety hereby agrees that its obligation will remain in full force and effect up to and including the date 28 days after the date of expiration of the Bid validity as stated in the Invitation to Bid or extended by the Purchaser at any time prior to this date, notice of which extension(s) to the Surety being hereby waived.

IN TESTIMONY WHEREOF, the Principal and the Surety have caused these presents to be executed in their respective names this ..... day of ..... 20 .....

Principal: ..... Surety: .....

Corporate Seal (where appropriate)

.....	.....
(Signature)	*(Signature)*
(Printed name and title)	*(Printed name and title)*

[1] The amount of the Bond shall be denominated in the currency of the Purchaser's country or the equivalent amount in a freely convertible currency.

Form of Contract Agreement

THIS CONTRACT AGREEMENT is made

the *[insert: number]* day of *[insert: month]*, *[insert: year]*.

BETWEEN

(1) *[insert: Name of Purchaser]*, a *[insert: description of type of legal entity, for example, an agency of the Ministry of .... of the Government of [insert: country of Purchaser],* and having its principal place of business at *[insert: address of Purchaser]* (hereinafter called "the Purchaser"), and

(2) *[insert: name of Supplier],* a corporation incorporated under the laws of *[insert: country of Supplier]* and having its principal place of business at *[insert: address of Supplier]* (hereinafter called "the Supplier").

WHEREAS the Purchaser invited bids for certain contraceptives and ancillary services, viz., *[insert: brief description of contraceptives and services]* and has accepted a bid by the Supplier for the supply of those contraceptives and services in the sum of *[insert: contract price in words and figures]* (hereinafter called "the Contract Price").

NOW THIS AGREEMENT WITNESSETH AS FOLLOWS:

1. In this Agreement words and expressions shall have the same meanings as are respectively assigned to them in the Conditions of Contract referred to.
2. The following documents shall constitute the Contract between the Purchaser and the Supplier, and each shall be read and construed as an integral part of the Contract:

This Contract Agreement

Special Conditions of Contract

General Conditions of Contract

Technical Requirements (including Technical Specifications)

The Supplier's bid and original Price Schedules

The Purchaser's Notification of Award

[Add here: any other documents]

3. In consideration of the payments to be made by the Purchaser to the Supplier as hereinafter mentioned, the Supplier hereby covenants with the Purchaser to provide the contraceptives and Services and to remedy defects therein in conformity in all respects with the provisions of the Contract.
4. The Purchaser hereby covenants to pay the Supplier in consideration of the provision of the contraceptives and the remedying of defects therein, the Contract Price or such

other sum as may become payable under the provisions of the Contract at the times and in the manner prescribed by the Contract.

For and on behalf of the Purchaser

Signed: .....

in the capacity of *[insert: title or other appropriate designation]*

in the presence of .....

For and on behalf of the Supplier

Signed: .....

in the capacity of *[insert: title or other appropriate designation]*

in the presence of _.....

CONTRACT AGREEMENT

dated the *[insert: number]* day of *[insert: month]*, *[insert: year]*

BETWEEN

[insert: name of Purchaser], "the Purchaser"

and

[insert: name of Supplier], "the Supplier"

Performance Security Bank Guarantee

……

[insert: Bank's Name, and Address of Issuing Branch or Office]

Beneficiary: ……

[insert: Name and Address of Purchaser]

Date: ……

PERFORMANCE GUARANTEE No.: ……

We have been informed that *[insert: name of Supplier]* (hereinafter called "the Supplier") has entered into Contract No. *[insert: reference number of the contract]* dated …… with you, for the supply of *[insert: description of goods]* (hereinafter called "the Contract").

Furthermore, we understand that, according to the conditions of the Contract, a performance guarantee is required.

At the request of the Supplier, we *[insert: name of Bank]* hereby irrevocably undertake to pay you any sum or sums not exceeding in total an amount of *[insert: amount in figures]* (……) *[insert: amount in words]*[1] upon receipt by us of your first demand in writing accompanied by a written statement stating that the Supplier is in breach of its obligation(s) under the Contract, without your needing to prove or to show grounds for your demand or the sum specified therein.

This guarantee shall expire no later than the …… day of ……., 2……,[2] and any demand for payment under it must be received by us at this office on or before that date.

This guarantee is subject to the Uniform Rules for Demand Guarantees, ICC Publication No. 458, except that subparagraph (ii) of Sub-article 20(a) is hereby excluded.

……

[signature(s)]

[1] The Guarantor shall insert an amount representing the percentage of the Contract Price specified in the Contract and denominated either in the currency(ies) of the Contract or a freely convertible currency

[2] Established in accordance with Clause 8.4 of the General Conditions of Contract ("GCC"), taking into account any warranty obligations of the Supplier under Clause 15.2 of the GCC intended to be secured by a partial performance guarantee. The Purchaser should note that in the event of an extension of the time to perform the Contract, the Purchaser would need to request an extension of this guarantee from the Guarantor. Such request must be in writing and must be made prior to the expiration date established in the guarantee. In preparing this guarantee, the Purchaser might consider adding the following text to the form, at the end of the penultimate paragraph: "The Guarantor agrees to a one-time extension of this guarantee for a period not to exceed [six months] [one year], in response to the Purchaser's written request for such extension, such request to be presented to the Guarantor before the expiry of the guarantee."

Bank Guarantee Form for Advance Payment

.....*[insert: Bank's Name, and Address of Issuing Branch or Office]*

Beneficiary: .....
[insert: Name and Address of Purchaser]

Date: .....

ADVANCE PAYMENT GUARANTEE No.: .....

We have been informed that *[insert: name of Supplier]* (hereinafter called "the Supplier") has entered into Contract No. *[insert: reference number of the contract]* dated ..... with you, for the supply of *[insert: description of goods]* (hereinafter called "the Contract").

Furthermore, we understand that, according to the conditions of the Contract, an advance payment in the sum *[insert: amount in figures]* (.....) *[insert: amount in words]* is to be made against an advance payment guarantee.

At the request of the Supplier, we *[insert: name of Bank]* hereby irrevocably undertake to pay you any sum or sums not exceeding in total an amount of *[insert: amount in figures]* (.....) *[insert: amount in words]* upon receipt by us of your first demand in writing accompanied by a written statement stating that the Supplier is in breach of its obligation under the Contract because the Supplier used the advance payment for purposes other than toward delivery of the contraceptives.

It is a condition for any claim and payment under this guarantee to be made that the advance payment referred to above must have been received by the Supplier on its account number ..... at ..... *[insert: name and address of Bank]*.

This guarantee shall expire, at the latest, upon our receipt of copy(ies) of .....,[1] or on the ___ day of _____, 2___,[2] whichever is earlier. Consequently, any demand for payment under this guarantee must be received by us at this office on or before that date.

This guarantee is subject to the Uniform Rules for Demand Guarantees, ICC Publication No.458.

.....
[signature(s)]

[1] Insert documents establishing "delivery" of the goods in accordance with the particular Incoterm selected. (See SCC 11.)

[2] Insert the delivery date stipulated in the original delivery schedule. The Purchaser should note that in the event of an extension of the time to perform the Contract, the Purchaser would need to request an extension of this guarantee from the Guarantor. Such request must be in writing and must be made prior to the expiration date established in the guarantee. In preparing this guarantee, the Purchaser might consider adding the following text to the form, at the end of the penultimate paragraph: "The Guarantor agrees to a one-time extension of this guarantee for a period not to exceed [six months][one year], in response to the Purchaser's written request for such extension, such request to be presented to the Guarantor before the expiry of the guarantee."

Certificate of a Pharmaceutical Product[1]

This certificate conforms to the format recommended by the World Health Organization *(general instructions and explanatory notes attached).*

No. of certificate: .....

Exporting (certifying) country: .....

Importing (requesting) country:.....

1. Name and dosage form of product:

.....

1.1 Active ingredients[2] and amount(s) per unit dose.[3]

.....

.....

.....

For complete qualitative composition including excipients, see attached.[4]

1.2 Is this product licensed to be placed on the market for use in the exporting country?[5] yes/no *(key in as appropriate)*

1.3 Is this product actually on the market in the exporting country? yes/no/unknown *(key in as appropriate)*

If the answer to 1.2 is yes, continue with section 2A and omit section 2B.

If the answer to 1.2 is no, omit section 2A and continue with section 2B.[6]

2A.1 Number of product license[7] and date of issue:

.....

2A.2 Product-license holder (name and address):

.....

.....

.....

2A.3 Status of product-license holder:[8] a/b/c *(key in appropriate category as defined in note 8)*

2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are: [9]

.....

.....

.....

2A.4 Is Summary Basis of Approval appended?[10] yes/no *(key in as appropriate)*

2A.5 Is the attached, officially approved product information complete and consonant with the license?[11] yes/no/not provided *(key in as appropriate)*

2A.6 Applicant for certificate, if different from license holder (name and address):[12]

2B.1 Applicant for certificate (name and address):

2B.2 Status of applicant: a/b/c *(key in appropriate category as defined in note 8)*

2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form are:[9]

.....

.....

.....

2B.3 Why is marketing authorization lacking?

not required/not requested/under consideration/refused *(key in as appropriate)*

2B.4 Remarks:[13]

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?

yes/no/not applicable[14] *(key in as appropriate)*

If no or not applicable, proceed to question 4.

3.1 Periodicity of routine inspections (years): _

3.2 Has the manufacture of this type of dosage form been inspected?

yes/no *(key in as appropriate)*

3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization?[15]

yes/no/not applicable[16] *(key in as appropriate)*

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? [11]

yes/no *(key in as appropriate)*

If no, explain: .

.....

Address of certifying authority: ____

Telephone number: __ Fax number: __

Name of authorized person:

.....

Signature:

.....

Stamp and date:

.....

General instructions

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the Scheme.

The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten.

Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

Explanatory notes

[1] This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.

[2] Use, whenever possible, international nonproprietary names (INNs) or national nonproprietary names.

[3] The formula (complete composition) of the dosage form should be given on the certificate or be appended.

[4] Details of quantitative composition are preferred, but their provision is subject to the agreement of the product-license holder.

[5] When applicable, append details of any restriction applied to the sale, distribution, or administration of the product that is specified in the product license.

[6] Sections 2A and 2B are mutually exclusive.

[7] Indicate, when applicable, if the license is provisional or if the product has not yet been approved.

[8] Specify whether the person responsible for placing the product on the market:

(a) manufactures the dosage form;

(b) packages and/or labels a dosage form manufactured by an independent company; or

(c) is involved in none of the above.

[9] This information can be provided only with the consent of the product-license holder or, in the case of non-registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the product license. If the production site is changed, the license must be updated or it will cease to be valid.

[10] This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.

[11] This refers to product information approved by the competent national regulatory authority, such as a Summary of Product Characteristics (SPC).

[12] In this circumstance, permission for issuing the certificate is required from the product-license holder. This permission must be provided to the authority by the applicant.

[13] Please indicate the reason that the applicant has provided for not requesting registration:

(a) The product has been developed exclusively for the treatment of conditions—particularly tropical diseases—not endemic in the country of export.

(b) The product has been reformulated with a view to improving its stability under tropical conditions.

(c) The product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import.

(d) The product has been reformulated to meet a different maximum dosage limit for an active ingredient.

(e) Any other reason, please specify.

[14] Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

[15] The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations (WHO Technical Report Series, No. 823, 1992, Annex 1). Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).

[16] This section is to be completed when the product-license holder or applicant conforms to status (b) or (c) as described in note 7 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.

Appendix V: Summary Guide for Policymakers, Directors and Managers

A. Introduction

Successful procurement and management of contraceptives, pharmaceuticals and other commodities is crucial to the success of reproductive health (RH) programmes because they require uninterrupted supplies of safe, effective products. "Uninterrupted" is a key word for these products, as they must be used on a regular basis in order to be effective and provide the required protection. Programmes that cannot support regular use of contraceptives do not achieve their objectives, acquire a poor reputation and soon lose their clients.

Developing and transitional countries have a great need for dependable RH services in the public sector, but in these same countries, public sector procurement can be a challenging job, often encumbered by problems and delays that generate stock-outs.

The skill and speed with which the supply process is handled is limited by the environment in which it operates. This environment includes laws and regulations, resources and infrastructure, routine practices of the government apparatus, and decisions made by those in authority.

Policymakers at every level have an impact on this all-important environment, either positively or negatively.

This Summary is written for:

1. Policymakers who are part of larger government bodies and heads of ministries or administrative units serving as legislative delegates, as well as higher-level government officials. This group may have little or no specific exposure to RH issues in general and procurement of contraceptives and pharmaceuticals in particular. They may never have considered how the quality and timeliness of these products affect the "greater good" of the people they are pledged to serve.
2. Personnel who sometimes become involved in parts of the RH supply process—generally the budgeting and financial aspects—but may not be aware of RH supply goals, good public sector procurement practices or operational details within their own systems that can affect the quality and timeliness of RH supplies.
3. Others who may find this summary useful as a supplement to the detailed learning modules.

For convenience, the remainder of this Summary Guide will include all audiences under the general heading of "policymaker."

The objective of this Summary Guide is to help readers develop the insight necessary to effectively support the primary goals of RH supply: *safety, efficacy, and timely delivery of the product.* To help achieve this objective, the Guide addresses the following key topics:

- Identifying where policymakers have an impact on RH supply.
- Identifying what policymakers need to know about RH supply.
- Providing an overview of the RH supply process.
- Identifying issues that lead to delays and other problems in the RH supply process.

A general understanding of pertinent processes and key issues will hopefully lead to beneficial decisions, or at least to decisions that will cause no harm. The Guide also seeks to instill realistic expectations about RH supply matters.

B. Where Policymakers Have an Impact on Reproductive Health Supply

The following are some of the key areas in which policymakers can have an impact—either favourably or unfavourably depending on the decisions made—on the overall effectiveness and efficiency of the RH supply process:

- Drafting and enforcing public procurement laws and regulations, including anticorruption measures.
- Interpretation of policies on fair competition. For example, World Health Organization (WHO) pre-qualification as a quality assurance (QA) measure is sometimes challenged inappropriately as limiting competition.
- Staffing policy can negatively impact personnel in procurement positions (e.g., routine rotations sometimes lead to untrained, inexperienced procurement personnel or personnel lacking specific knowledge required for RH product procurement).
- Budget allocations:
  - Financing and support for staffing and internal infrastructure.
  - Financing for product procurement.
- Management of funds (allocated funds are sometimes unavailable when the obligation to the supplier must be paid).
- Efficient, timely decision-making and approval processes.
- Building reputations for trouble-free international commerce and fair competition, which attracts good suppliers and increases competition.
- Taxation policy. (Must a programme pay taxes on goods that will be used in the public sector?)
- Regulatory and product licensing issues and procedures.

- Import procedures and restrictions.
- Disposal of expired or defective goods.
- Inspection and acceptance policy.
- Centralized versus decentralized procurement.

While generally left to the responsible program manager, other policymakers may play a part in decisions about:

- Finalizing quantification data.
- Determining the method mix for contraceptives.
- Allocating budgets and other resources.
- Adding new products to the essential medicines list.
- Selecting the procurement option (e.g., procurement handled directly by staff or indirectly through an external organization).
- Assigning procurement responsibility.

C. What Policymakers Need to Know About Reproductive Health Supply/Contraceptives

1. What Are "Reproductive Health Goods" and Where Do They Come From?

WHO publishes *The Interagency List of Essential Medicines for Reproductive Health*, which presents the current international consensus on the rational selection of essential RH goods and medicines.[1] This list includes a wide range of pharmaceutical goods and medicines, from anesthetics and anti-infective medicines to disinfectants, contraceptives and immunologicals that have been selected to provide comprehensive reproductive health medical care.

For this Summary Guide, this list of RH goods and medicines has been narrowed to focus primarily on contraceptives, which include hormonal contraceptives in pill or injectable form, intrauterine devices, implants and condoms.

The technology required to produce contraceptives ranges from highly sophisticated steroid synthesis and compounding to factory floor injection molding and latex dipping—all very different manufacturing environments requiring specialized, expensive equipment and quality control measures that often rule out local production in developing economies. Some of the pharmaceuticals are more likely to be produced locally in developing countries.

a. What This Means for the Reproductive Health Supply System

[1] World Health Organization (WHO), *et. al. The Interagency List of Essential Medicines for Reproductive Health*. Geneva: WHO; 2006. Available at: http://www.who.int/medicines/publications/essentialmedicines/WHO-PSM-PAR-2006%20I_Rev.pdf.

Most contraceptive purchases involve doing business with international manufacturers. This requires managing the transfer of funds through the international banking system and observing international trade conventions. It also brings into play widely recognized standards for public procurement; these are reflected in the expectations of potential suppliers. Import procedures and customs clearing systems enter the picture, as do licensing and regulatory issues. The supply process will be interrupted if any of these functions are performed poorly.

2. Overarching Requirements: Quality and Timeliness

a. Quality

In purchasing products for the RH programme, safety and efficacy take precedence over cost. In this special area of health, a poor quality product has the capacity to do irreparable harm and, at the very least, waste public money by doing nothing at all. Unfortunately, unscrupulous sellers are found in many countries, selling fake, outdated and substandard products to unsuspecting buyers at very low prices. In any situation, "bargain" prices can be an indicator of poor quality products.

For this reason, in all budgeting exercises for RH contraceptives, it is necessary to incorporate measures to ensure the quality and efficacy of the product.

b. Timeliness

As explained earlier, RH programmes must be able to support regular use of contraceptives by their clients. The procurement process incorporates measures to promote timely, dependable re-supply, but the outcome is always vulnerable to problems in the wider environment.

3. Quantity Implications

A single unit or even a month's worth of a contraceptive product is a minimal investment, but the annual quantity requirements for a target population add up to relatively high values.

a. What This Means for Reproductive Health Supply

1. Potential suppliers can become forceful when high values are at stake. They may attempt bribery or other corrupt practices, which, if successful, may drive away potential bidders in the next round of RH procurement. Or, unsuccessful competitors may try to subvert award decisions that are not in their favour—leading to long delays.
2. Rules for government and organizational spending are most stringent at high financial "thresholds," meaning the procurement process for contraceptives is likely to be lengthy and complex.

4. Regulation of Reproductive Health Goods by National Regulatory Authorities

Regulatory licensing by national regulatory authorities (NRAs) is primarily a means of protecting populations from unsafe, ineffective, poor quality and costly contraceptives, drugs and medical devices.

Worldwide, manufacturers of drugs and contraceptives must apply to local regulatory authorities for permission to market or otherwise distribute their products in a country by submitting safety and efficacy data and samples. The local NRA reviews these data, does testing and grants or refuses licensing in a process that is often time consuming and expensive for the manufacturer. Thus, licensing a product is usually not undertaken unless the manufacturer is relatively sure of obtaining a market share in the target country.

Enforcement of regulatory licensing is handled in part by national customs services; unlicensed products are denied entry into a country, turned back or quarantined and eventually destroyed.

a. What This Means for Reproductive Health Supply

Since most developing countries need to import contraceptives, local regulatory licensing is critical. Good public sector policy on competition requires the purchasing authority to accept bids from all potential suppliers, not just those offering already licensed products. Should the bidder of an unregistered product win the competition, the manufacturer of the offered product must obtain licensing (marketing authorization) from the local regulatory authority before a contract can become effective. The problem that arises has to do with the length of time it takes for such licensing and whether or not it will delay delivery enough to impact the supply situation. Some governments have dealt with this problem at the policy level by approving a "fast-track" regulatory procedure that accepts evidence of licensing in countries with known stringent regulatory authorities in lieu of prolonged and detailed investigations into the product's safety and efficacy by the local authority.[2]

5. Principles of Good Public-Sector Procurement

Good public sector procurement is based on competitive bidding and a fair, well-documented supplier selection process. Development banks and donors around the world, as well as many governments, require these widely held standards and procedures of entities using their funds. In the past, details have varied by institution, but in recent years, the Organisation for Economic Co-operation and Development has spearheaded a movement to harmonize rules, procedures, and documents across their membership. Health sector procurement involves additional product challenges. Products such as contraceptives,

[2] For example, countries that are members of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) have known stringent regulatory authorities. For more information on the PIC/S and ICH, see Supplementary Topics, Section K: Regulatory Authorities.

pharmaceuticals and vaccines have unique QA and regulatory requirements that are added to the normal provisions for public sector procurement.

6. Who Works on Reproductive Health Supply?

In a traditional setting, programme personnel (usually with public health backgrounds) are responsible for programme planning tasks, and a separate procurement unit is responsible for procurement process tasks. In addition, critical contributors, such as the Ministry of Finance, pharmacy specialists, the RH unit, accounting, customs clearing and central stores play peripheral but important roles.

It is not uncommon to see programme management doing some of the procurement processing tasks and vice versa; the work can be divided in any way that suits the situation, as long as the assigned personnel have appropriate skills and product knowledge.

7. How Long Should it Take to Purchase Reproductive Health Goods?

Faster is not always better when it comes to quality and cost. Twelve months or more may elapse from the time funding is assured until goods are ultimately delivered—even under a well-run international competition. The skill and diligence of the procuring entity are important factors in minimizing the time it takes to purchase RH goods, but they are not the entire story. Bottlenecks often occur in areas over which the procuring entity has no control. For example, approvals may be held up due to the absence or distraction of a key individual.

8. Financing the Annual Reproductive Health Goods Requirement

Funds for procurement of RH contraceptives may come from a government's own revenue budget, loans or grants from development banks (e.g., the World Bank), a bilateral donor arrangement, foundation gifts, etc. *Confirmed funding—regardless of the source—is the most critical link in the RH supply process.* In addition, the source of funding may dictate how the procurement should proceed, who should do it and what markets can be solicited for offers. A government health programme using its own revenue funds may require its centralized national procuring entity to carry out a competitive bidding process for its requirements.

D. The Reproductive Health Supply Process

There are three phases of the RH supply process: programme planning, procurement process and contract performance. Each phase is composed of different elements. The table below is a visual representation of the process.

Three Phases	Ten Elements
I. Programme Planning	Defining Reproductive Health Supply Requirements
	Specifications
	Assessment of Procurement Options
	Budget, Funding and Procurement Requisition
Critical Link: Funded Procurement Requisition	
II. Procurement Process	Procurement Planning
	Developing Bidding Documents and Inviting Offers
	Selecting Suppliers
	Contracts
Critical Link: Signed Contract and Payment Guarantee	
III. Performance	Contract Performance and Monitoring
	Delivery of Goods
Critical Conclusion: Delivery and Acceptance of High-Quality Products	

Critical components link each stage in the supply process:

- Funding
- Signed contract
- Payment guarantee
- Delivery of high quality products

Failure at any critical link will terminate the supply process.

Additional details regarding the elements within each phase of the supply process and the critical components linking each phase can be found in the individual modules of the Toolkit.

Phase I: Programme Planning

The first time a new policymaker becomes aware of the RH supply programme is often during preparation and discussion of the annual budget. Budget requests for RH commodities are usually the result of a long, iterative process of planning and decision-making. The first part of the process is requirements definition, followed by cost estimation and, finally, the establishment of a budget requirement.

The modules addressing the elements of the programme planning phase are as follows.

Element 1. Defining Reproductive Health Supply Requirements
This is the process of selecting the appropriate products and forecasting the quantities to be purchased. These processes are based on programme coverage goals, method mix, existing inventories, required delivery dates and other programme factors.

Element 2. Specifications
Technical specifications are one of the most important elements of procurement:

- They provide detailed information to suppliers about the goods to be purchased.
- They are the benchmarks against which the purchaser will judge the technical responsiveness of suppliers' bids.
- They form the basis for the contractual obligation of the supplier to the purchaser.
- They are the criteria against which the purchaser will determine the acceptability of specific goods prepared by the supplier for shipment.

Specifications can be used to define a variety of areas, such as product information (quantity, size, colour and registration), manufacturing requirements (standards for raw materials and current good manufacturing practices certification), testing requirements and packaging and shipping requirements—all details that when taken as a whole ensure product quality and acceptability to the end user.

In addition to specifications that are clear, accurate and complete, public sector procurement requires that specifications be prepared in a way that will encourage maximum competition. They must be "product neutral". In other words, they must use generic terms, relative characteristics and performance requirements rather than brand names and superficial descriptions. If there is no way to avoid stating a brand name, it must be followed by "or equivalent". Non-functional requirements (such as colour and exact dimensions) must have strong justification and may not be used simply to eliminate all but a specific brand.

A challenge and requirement at this phase is to manage the process to ensure specifications are complete, comprehensive and accurate, including obtaining input from all relevant governmental bodies, technical specialists, and programme staff.

Element 3. Assessment of Procurement Options

Most organizations choose one of the following approaches when assessing their procurement options:

- Contract directly with a manufacturer (or its agent).
- Purchase goods from a distributor that has contracted with manufacturers for large quantities which it resells.
- Hire a procurement agent to purchase goods on their behalf.

The choice directly affects cost, so it must be considered when developing a budget. Contracting directly with a manufacturer or its agent usually returns the lowest unit price, but requires the most expertise. The decision is made based on what is possible, what is practical, who can/will do the procurement work and cost implications. In many cases, a program will use different options for different products. Programme managers normally decide on the best course of action for their circumstances; however, organizational and government policies play a role.

The two main options, direct procurement and indirect procurement, and their variations are shown below. Some of the requirements for each, plus financial commitments and risk factors, are summarized in Exhibit S-1.

Exhibit S-1: Procurement Options Table

Requirements and Results for the Reproductive Health Purchaser							
Procurement Option	Purchase Quantity	Foreign Exchange Required	Procurement Skills Required[1]	Infrastructure[2]	Product Cost	Fee[3]	Risk Level[4]
Direct -international bid	Large	Yes	High	High	Low	No	Low
Direct -international bid with private agent	Large	Yes	Med	Med	Med	Yes	Med
Indirect - public procurement agency	Large	Yes	Low	Low	Med	Yes	Low
Indirect -private procurement agent	Med to large	Yes	Med	Med	High	Yes	Med
Indirect -parastatal procurement service	Any	No	Low	Low	High	Yes	High
Indirect -regional buying alliance	Any	Yes	Low	Med	Med	Yes	Med

[1] Required level of procurement skills needed to administer the procurement option.

[2] Ministry of Health infrastructure required to support procurement.

[3] Fee included in the cost.

[4] Risk of a poor quality product. Risk level is based on product knowledge, skill of agent and proper administration.

a. Direct Procurement

- International competition
- International competition using a private procurement agent
- Sole-source procurement
- Small-scale national competition

b. Indirect Procurement
   - International supply service
     - Public sector agency (e.g., UNFPA, UNICEF)
     - Private sector agency (e.g., IDA Foundation, Missionpharma)
   - International procurement agency (the private-sector Crown Agents)
   - Parastatal procurement service
   - Regional buying alliance (where one exists)

Element 4. Budget, Funding and Procurement Requisition

a. Cost Estimates

   Cost estimates are not as straightforward as they might seem. Prices for each product vary widely based on how the procurement is done (see the procurement options above) and the level of the supplier in the distribution chain. Moving down the distribution chain (from manufacturer to retail seller) adds costs and a profit margin at each level that is passed on to the purchaser. In addition, discounted public sector prices are available for some products from some international suppliers and manufacturers. Access to these special prices is usually tied to a country's gross national income (GNI), with the poorest countries paying the lowest prices. Large-quantity purchases often rate discounted pricing as well. Thus, the lowest prices may be seen when a low GNI country is purchasing large quantities from a high level of the distribution chain. The GAVI Alliance provides support to national governments to procure discounted vaccines through the GAVI Fund. Eligibility is determined by national income, and only countries with a GNI per capita of less than US$1,000 in 2003 qualify. Currently, there are 72 eligible countries.[3]

b. Assessment of Supply Possibilities

   In order to develop useful cost estimates, the procuring entity must determine the types of sellers available to it for each product. Supply possibilities are dependent on issues such as:

   - Access to convertible currency and banking for international purchases
   - Agreements with financing organizations
   - National trade barriers
   - Regulatory constraints
   - What level of supplier is likely to be interested based on quantity requirements and expenditure levels

c. Pricing Research

   The procuring entity must also research current product pricing information and associated costs. The following resources can be used for this purpose:

[3] For more information, see http://www.gavialliance.org/support/who/index.php.

- Quantities and last prices paid
- Direct inquiries to manufacturers
- Published price guides
- United Nations agency pricing
- Discounted pricing, if eligible (low GNI)
- Associated costs, including:
  - Taxes and fees
  - Freight and insurance costs and modality of last shipments
  - Inspection and testing
  - Inland transport

d. Calculating the Budget Requirement

The estimated cost to fulfill the coverage target is calculated by multiplying each item by its likely price and adding associated costs. If the estimated cost is more than the amount likely to be available—as is often the case in developing countries—the RH programme must make adjustments to the number of clients it can serve, delay some of the procurement and draw down on buffer stock (if any exists), or find additional funding. See Module 4 for additional information on budgeting.

e. Procurement Requisition

Once funding has been assured, the programme requiring RH products can issue a procurement requisition to the entity responsible for procuring the goods, providing detailed information about product requirements by item, quantity, delivery date, and technical specifications.

Phase II: Procurement Process

Between funding a procurement request and a signed contract lies a large body of decision-making and prescribed activity generally referred to as the "procurement process".

Element 5. Procurement Planning

The procuring entity selects an appropriate method for purchasing the required goods if it has not been specified by the financing organization in policies tied to financial thresholds. For contraceptives, the procurement method is usually international competitive bidding either open to all or restricted to products and manufacturers that have been prequalified in some manner.

Procurement planning also establishes expectations for a delivery date, a time frame for payment and a framework for monitoring progress.

Element 6. Developing Bidding Documents and Inviting Offers

Bidding documents contain rules and conditions for bidding, state how a winning bidder will be chosen and prescribe conditions of the resulting contract (including the method of payment). They also include formal specifications, quantity requirements and a delivery schedule. Under good public sector procurement practice, everything must be clearly stated; nothing can be changed once the bids are opened, so the process of developing bidding documents necessarily requires many careful decisions. At times, the procuring entity will need information or a decision from the policymaker level before it can proceed. Delays in obtaining information and decisions can easily translate into a delayed procurement process and critical shortages in the supply chain. In addition, failure to incorporate product quality protection into bidding documents and subsequent contracts can result in receipt of substandard products.

Most governments and organizations use model (standard) bidding documents that contain mandatory wording in line with official policy. Clauses specific to the procurement are filled in by the procuring entity. Finished documents are often more than 50 pages long once all the necessary schedules and bidding forms have been included, and they are sometimes difficult for casual readers to understand.

After the bidding documents have been prepared and approved, the procuring entity alerts potential suppliers about the opportunity to bid. This is done through advertisements in local and national publications as well as on public access websites and bulletin boards. Sometimes trade organizations are also notified.

Bidding documents are numbered and sold upon request to potential bidders at a nominal cost—enough to ensure that the party is actually interested in bidding, but not so much as to restrict competition. The purchasing office records contact information for everyone who receives bidding documents so they can be notified in the event of amendments, special meetings, etc.

Offers—or bids—may start arriving shortly after bidding documents are made available and continue up until a preestablished closing date. However, these bids cannot be opened and must be securely stored until the time and place indicated in the bidding documents. At that time, they are opened in public, often by a specially appointed bid opening committee. Basic, pertinent data such as price, delivery date and the bidder's name and country are announced, but a winning bid is not identified at this time for two reasons: price is rarely the only determinant in selecting a supplier, and the prices indicated by bidders may not be fully comparable.

Element 7. Selecting Suppliers

In most public sector systems, suppliers are selected by special committees convened for that purpose and chaired by a relatively high-level official. Procurement personnel may help with the paperwork, but the committees are responsible for examining, evaluating and

comparing the offers, and finally agreeing on the best one. In public sector procurement, this is a strict process guided by evaluation criteria announced in the bidding documents in advance. International suppliers expect the selection process to adhere to the stated evaluation criteria, so problems are likely if the selection is based on ministerial privilege or anything other than the evaluation criteria.

After the best offer has been determined, the financial, commercial and technical background of the apparent successful bidder (and one alternate) will usually need to be checked to make sure the company has the capacity and capability to perform the contract.

Approvals at higher levels of an organization or government are generally required before an actual award can be made. Unfortunately, bottlenecks that delay the delivery schedule are often seen in this step.

Element 8. Contracts

After the supplier has been selected, the contract needs to be prepared, signed and awarded. Often, there is a time limit for obtaining signatures. This activity also includes deciding on payment methods.

The first responsibility for contract execution lies with the purchaser, which provides some type of payment guarantee to the supplier. Particularly in trade with developing countries, manufacturers usually do not enter an order into production until this payment guarantee is in place. Producers frequently have a backlog of orders for products in high demand (e.g., condoms), so quickly establishing the payment guarantee keeps the delivery date on track. The most prevalent guarantee is a commercial letter of credit (L/C) opened at a reputable international bank by the purchaser in favor of the seller. The purchaser deposits money in the bank to "collateralize" the L/C; the bank holds it until the seller provides documentary evidence that it has complied with the terms and conditions of the L/C. More information about L/Cs and payment methods can be found in Annexure 3 in the Basics Module of this Manual.

Phase III: Performance

In the performance phase of the RH supply process, the procuring entity monitors the supplier's performance, including arranging for preshipment inspection of contraceptives, customs clearance upon arrival at the port of entry, and delivery to the receiving warehouse.

Element 9. Contract Performance and Monitoring

Contracts for contraceptives may require independent inspection of the goods at the supplier's facility when they are ready for shipment. This helps to ensure that incoming products are in good condition, packaged and labelled properly and are being supplied in the correct quantities. For condoms, a sample is drawn and sent to an independent laboratory for quality testing as well. Condom testing discourages marginal suppliers from providing poor quality products that malfunction during use. For more information, please refer to

WHO's *The Male Latex Condom: Specification and Guidelines for Condom Procurement*[4] and to Supplementary Topics, Section I: Product Inspection and Testing.

One of the ways contraceptive purchasers can enforce QA requirements is by requiring a Certificate of Clean Findings as part of the L/C evidence mentioned above. If the supplier cannot provide the required certificate for the bank, the bank will determine that it has not fulfilled the terms and conditions and will not release the payment.

Element 10. Delivery of Goods

Public sector contraceptives are normally shipped via ocean unless the supply source is close enough for trucking. Both of these options are far less expensive than air, which is usually reserved for emergency situations.

At the port of entry, goods are inspected for damage and, in the case of contraceptives and pharmaceuticals, their regulatory licensing status is appraised. The procuring entity may hire a customs clearance agent to carry out necessary paperwork and obtain a release from customs. When this is not accomplished within a few days, demurrage (storage) charges are applied by the port authority, which can add up to significant amounts.

Upon release from customs, it is up to the purchaser to transport the goods to its own warehouse. Some customs clearance agents will make this arrangement, and sometimes a local representative of the supplier will do it. In most cases, the purchaser sends its own trucks or hires private transport.

Once delivered to the initial warehouse, personnel perform a receiving inspection, confirming that all goods are present according to the accompanying packing lists, are in good condition and that product names and expiry dates are clearly marked.

E. Issues That Create Significant Delays and Other Problems in the Supply Process

This section identifies some of the common problems that occur in the supply process that can delay procurement and create product stock-outs. The Toolkit module(s) where additional information can be found on ways to address each problem is noted in parentheses.

1. Government Policy vs. Practical Application

a. Blanket Policy Devolving Procurement to Regional and Local Facilities

- Significance: Centralized procurement is a better option for contraceptives because it offers economies of scale and allows for better management of national stocks. In addition, contraceptives (in programme quantities) are usually imported, requiring skill and knowledge that is not commonly found below the central level.

[4] World Health Organization (WHO), United Nations Population Fund, Joint United Nations Programme on HIV/AIDS. *The Male Latex Condom: Specification and Guidelines for Condom Procurement*. Geneva: WHO; 2003. Available at: http://www.who.int/reproductivehealth/publications/family_planning/9241591277/en/.

- The result: Contraceptives purchased at regional and local levels can be expensive and often out of stock due to weak management. RH programme personnel may want to fight for centralized procurement of contraceptives as an exception to any blanket policy (decentralized supply is much more appropriate for pharmaceuticals, including those used in RH programmes).

b. Procurement Rules, Policies and Standard Bidding Document Clauses That Fail to Take into Consideration the Special Nature of Contraceptives.
   - Significance: Issues of concern when purchasing machinery and equipment (e.g., spare parts) do not apply to contraceptives and pharmaceuticals.
   - The result: Contracts without appropriate quality protections; confusion and/or protest on the part of bidders, leading to delayed delivery or cancellation of the bid.

c. Government Rules That Limit Financial Transactions to the Country's National Bank
   - Significance: It may be impossible to open a commercial L/C that will be honoured in another country.
   - The result: Cancellation of the contract due to lack of compliance on the part of the purchaser.

d. Blanket Government Regulations Prohibiting Cash in Advance as a Payment Modality
   - Significance: The rule is at odds with United Nations agency requirements.
   - The result: Option of purchasing contraceptives through UNFPA is eliminated unless a variance can be arranged (which usually takes a good amount of time).

e. Blanket Taxation on Imports
   - Significance: Takes money from one government pocket (public health) and puts it into another (general fund).
   - The result: The number of clients an RH programme can serve will be reduced.

f. Requiring That Certain Procurement-Related Activities Be Handled by a Different Ministry
   - Significance: Once out of the hands of the procuring entity, it is impossible to control timing. The procuring entity uses websites, bulletin boards and newspapers for the bid announcements in order to make sure the invitation reaches as many potential bidders as possible.
   - The result: It is almost impossible to comply with good public sector procurement policy that requires that all announcements of an opportunity to bid appear at the same time; bidders can lodge valid complaints that will probably delay the procurement process.

g. Mandatory Bidding Document Clauses (Approved at Ministerial Level) That Do Not Represent Normal Operating Procedures or the Actual Situation

- Significance: Requirements to perform in a certain way are embodied in the bidding documents.
- The result: Bidder protest and delayed procurement.

h. Government Hierarchy Rather Than Familiarity With a Specific Bid Requirement Determines the Chairperson for Pre-bid Meeting
- Significance: The chairperson controlling the meeting is unlikely to understand pertinent issues or the subject of the procurement.
- The result: Unproductive and sometimes poorly run pre-bid meeting; legitimate questions not answered promptly; confusion among potential bidders; potential for delaying the procurement process.

2. Programme-Level Decisions

a. Deciding to Use a Procurement Agent Without Someone on Staff Who Knows What Should Be Happening
- Significance: Someone needs to monitor the agent's performance.
- The result: Potential for oversights; noncompliant processes; delays; less than the best supply contract; money wasted (fees payable to the agent).

b. Failure to Take into Consideration Warehouse Capacity When Scheduling Shipments
- Significance: Inability to plan space for the shipments; creating a lost opportunity to solve problems before they occur.
- The result: Overcrowding or having to pay for additional space in another facility.

c. Accepting Donations (or Bargains) on Goods That Are Not Needed
- Significance: Excess goods fill up warehouse space needed for other products.
- The result: Overcrowding or having to pay for additional space in another facility.

d. Specifying and Planning on a Delivery Date Without Taking into Consideration the Normal Timeline for Procurement—12 Months
- Significance: False expectations.
- The result: Potential for stock-outs and no plan in place to cope with the realities of the stock situation; lost opportunity to prevent problems before they happen.

e. Failure to Act on Information and Constraints Uncovered During Planning Work That Will Affect What is Possible and How Long the Supply Process Will Take
- Significance: Flawed expectations.
- The result: Later deliveries; potential for stock-outs.

3. Financial, Budgeting and Accounting

a. Accounting System Not Showing Outstanding Commitments
- Significance: Overstated line item balances.
- The result: Some managers will use up funds that will be needed later.

b. Manager's Failure to Take into Consideration a Likely Time Frame for Payment Obligations (Module 5)
   - Significance: Funds may not be available when payment obligations are due.
   - The result: Delayed delivery; cancelled contract.

c. Lack of Provision for Access to Ready Cash for Minor Expenses
   - Significance: Alternative arrangements will be needed for:
     – Postage to send bidding documents to potential bidders located outside the immediate area of the procurement office.
     – Car fare to transport personnel on procurement-related business.
     – Minor expenses related to port clearing.
   - The result: Delays while alternative arrangements are being made add up to later delivery (and in the case of port clearing, a risk of demurrage charges), thus much higher costs.

d. Forgetting to Add in Associated Costs and Fees When Developing a Budget
   - Significance: Costs and fees will need to be paid whether they are budgeted or not.
   - The result: Not enough money to cover planned procurement; reduction in quantities/ shortages; using inappropriate prices for cost estimates; not understanding what is and is not included in representative prices.

e. Failure to Provide for Possible Currency Value Fluctuation When Budgeting for Goods That Are Likely to Come From a Foreign Source
   - Significance: Potential for increased cost.
   - The result: Not enough money to cover entire commodity requirement; reduction in quantities/shortages.

f. Funding Released Quarterly or Monthly
   - Significance: Funds will need to be accumulated in anticipation of future payment obligations. Requires very careful timing of procurement activity so contract signing does not occur before enough money is available to cover the payment guarantee.
   - The result: Potential for delayed delivery and stock shortages.

4. Bidding Documents

a. Not Including Special Handling Requirements in Contracts and Shipping Instructions
   - Significance: Goods may end up on an unprotected deck of a cargo ship in rough waters.
   - The result: Heat and moisture can damage oral contraceptives, condoms, etc.

b. Lack of Marking Instructions for Intermediate Boxes
   - Significance: Name of product and expiry date may be missing from cartons.
   - The result: Inefficient storage and stock handling; incorrect items delivered to service sites.

c. Bidding Documents Not Listing Exactly What Will Be Required for Entry into the Purchaser's Country
   - Significance: If proper documentation is not presented, shipment can be held at the port, returned or destroyed.
   - The result: Stock-outs—a good example of how a small oversight in bidding documents can turn into a supply disaster.

d. Last Minute Edits to a Bidding Document Clause That Are Not Carried Through to the Corresponding Clauses in Other Sections
   - Significance: Can change intended meaning.
   - The result: Confusion; need to amend bidding documents and/or extend the closing date; later deliveries.

e. Bidding Document Clauses That Include Commitments the Procuring Entity is Not at Liberty to Make and Cannot Support (Sometimes Seen With Regard to Regulatory Licensing)
   - Significance: False expectations on the part of bidders.
   - The result: Confusion; protest; later deliveries.

f. Bidding Documents That Require Samples of Pharmaceuticals and Contraceptives Be Submitted With Bids
   - Significance: Products to examine and test at extra time and cost.
   - The result: Samples of these products will not be representative of quality at a future point in time; however, a simple visual inspection can be useful to weed out potential suppliers that submit obviously inferior products (e.g., in oily or dirty packaging).

5. Interministerial/Interdepartmental Coordination

a. Lack of a Defined Chain of Authority
   - Significance: Procurement personnel need to know where to look for decisions and advice.
   - The result: Delayed production of bidding documents, etc.; later delivery dates.

b. Slow Approvals
   - Significance: Procurement process cannot advance without required approvals.
   - The result: Offers may expire while waiting for approval; extensions must be arranged, and the whole procurement process will be delayed, leading to later delivery and possible stock-outs.

c. Letter of Credit Copies Not Made Available to Procurement Staff by the Finance Unit
   - Significance: Omissions or mistakes on the L/C not detected and corrected.
   - The result: Costly later correction; L/C may not be useful as a means to ensure product quality.

d. Government "Short List" (of Service Providers) Does Not Include Appropriate Contraceptive Inspection and Testing Firms
   - Significance: Separate, lengthy bid process is required to establish them.
   - The result: Delayed supply process; lack of authorization to contract for associated services, such as inspection and testing.

e. Minimal Advertisement of the Invitation for Bids
   - Significance: Potential bidders are not aware of the opportunity so there is not enough competition to validate the bidding.
   - The result: Bidding exercise may need to be cancelled and rerun, leading to later deliveries; potential for stock-outs.

6. Evaluation Committees

a. Failure to Check the References of the Apparent Winning Bidder
   - Significance: Information provided by the bidder may not be entirely truthful.
   - The result: Possibility that the supplier will not perform adequately; late deliveries; poor quality.

b. Lack of Knowledge About How to Read Bidding Documents
   - Significance: Bidding documents contain all requirements about the goods, the bidder's eligibility and qualifications, and describe how evaluation and selection will take place.
   - The result: Faulty interpretation leading to erroneous judgment and potential protests lodged by unsuccessful bidders; delayed procurement; possible cancellation of the bid.

c. Misunderstandings About Interpreting Common Phrases Used in Procurement
   - Significance: Used in deciding if the bidder is qualified to perform the contract.
   - The result: Potential error in selection of the winning bid; erroneous award; potential protests lodged by unsuccessful bidders; delayed procurement; possible cancellation of the bid.

d. Delay in Identifying a Winning Bid
   - Significance: Bidders will need to be asked to extend the expiry date of their offers and bid securities; negative impact on the timeline.
   - The result: Later delivery; risk of stock-outs; poor reputation for the next round of bidding.

7. Stakeholder Perception

a. Misunderstanding the Time Frame Required for Procurement

- Significance: Stakeholders are often in some position of power as funders and contributors to RH programmes, so their opinions matter.
- The result: Negative impact on public procurement; unnecessary time and energy spent on helping peripheral individuals understand that public procurement requires at least 12 months from initiation to delivery and that "fault" cannot be tied to the efforts of any single office, as many players and situations have parts to play (the procurement staff itself cannot control, for example, how long an approval at the ministerial level might take).

F. Summary of Challenges

Policymakers should be aware of these challenges and do everything in their power to create policy that will overcome them. The following summarizes the key challenges found in each of the ten elements of the RH supply process.

1. Defining Reproductive Health Supply Requirements

- Ensuring the quality of the information gathered and the forecasts generated.
- The budget available for contraceptive procurement often drives procurement, rather than the other way around.

2. Specifications

- Obtaining or crafting comprehensive specifications in the format and technical language of the relevant industry (e.g., contraceptives, pharmaceuticals, condoms).
- Providing a clear, correct description of all regulatory requirements, including those of the relevant NRA.
- Ensuring that technical specifications are product neutral through the use of generic terms and relative characteristics.

3. Assessment of Procurement Options

- Understanding the options for procurement and the implications of each option.
- Honestly appraising the capabilities and environment of each option, even if findings are politically unflattering.

4. Budget, Funding and Procurement Requisition

- Developing reasonably accurate cost estimates for each item.
- Maintaining principles of good public sector procurement.

5. Procurement Planning

- Recognizing and working around potential conflicts and constraints in the environment or system.
- Determining how long each step in the procurement cycle is likely to take.

- Coordinating the procurement schedule with funds-release dates.
- Coordinating delivery dates with warehouse capacity and inventory requirements.

6. Developing Bidding Documents and Inviting Offers

- Building adequate product quality protections into the bidding documents.
- Neutralizing potential problems with the use of appropriate bidding document clauses.
- Making sure that what the bidding documents say is what will actually happen, thus reducing the chance of bidder protest, which can lead to delayed delivery.

7. Selecting Suppliers

- Maintaining principles and procedures of good public sector procurement: fair appraisal and evaluation of each offer, equitable comparison of all offers, and selection based on the lowest evaluated cost.
- Ensuring appropriate documentation and justification for selection and award.
- Ensuring that approvals are rendered without undue delay.

8. Contracts

- Ensuring that contracts contain the provisions necessary to obtain good quality products and provide adequate protection against a supplier's lack of performance.
- Ensuring timely contract award.
- Ensuring timely contract payment arrangements.

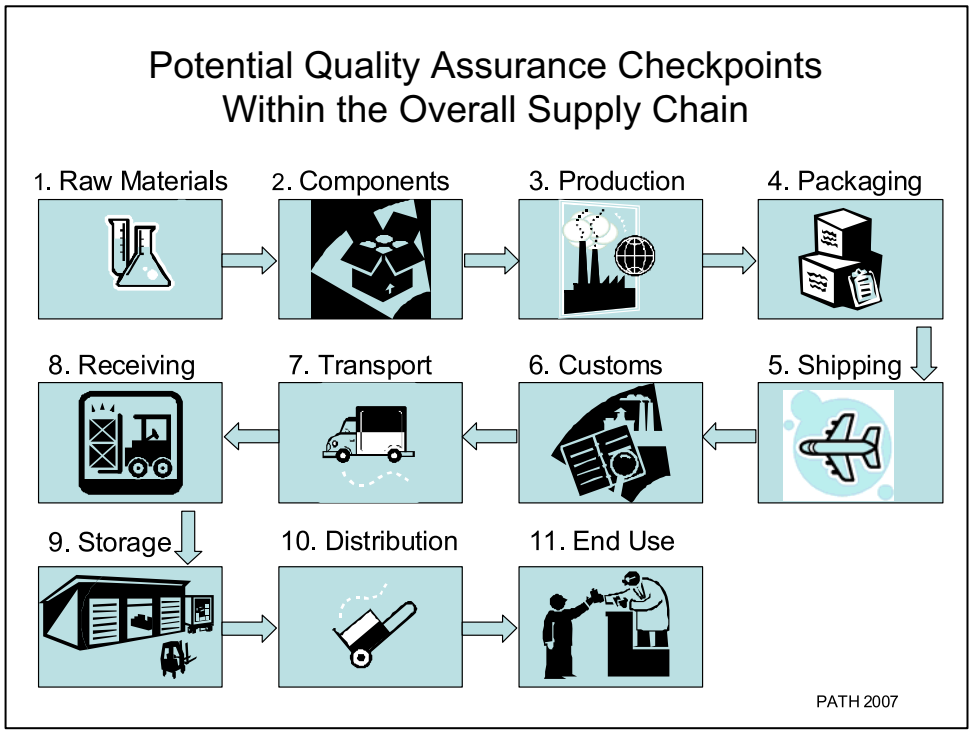
9. Contract Performance and Monitoring

- Eliciting supplier commitment to take contract compliance and monitoring seriously.
- Proactively implementing contract performance monitoring by the purchaser.

10. Delivery of Goods

- Understanding and supporting customs clearance requirements so that the clearance process is completed in a timely manner.
- Ensuring proper inspection of goods upon receipt at the receiving warehouse.

Appendix VI: Product Quality Assurance



This graphic provides a visual overview of the key activities that occur in the standard product supply chain. The overall life cycle of a medicine has several points where quality needs to be built in, from manufacturing to distribution. This graphic illustrates several activities in the product supply chain. Each of these points has the potential for quality risks as follows:

1. **Raw materials and components:** Poor quality or counterfeit raw materials; substandard components.
2. **Manufacturing:** Absence or problems with active ingredients; cross-contamination of other products made on same manufacturing line.
3. **Packaging:** Substandard packing materials that do not adequately protect; improper labeling on primary packages.
4. **Shipping:** Temperature sensitive products not shipped in proper environment (e.g., vaccines in cold chain).
5. **Customs:** Product not registered; missing or inconsistent documentation causing delays in clearance.

6. **Receiving:** Product not inspected for damage upon receipt; product not recorded properly in receipt logbook.
7. **Storage:** Product not stored in required environment; expiration date not monitored.
8. **End use:** Dispenser does not provide proper use and storage instructions; patient does not store product in required conditions.

Quality is ensured in the supply chain by the following key players:

- Raw materials suppliers
- Manufacturers
- National regulatory authorities
- Procurement units
- Logistics systems
- Service providers and end users

No individual agency bears the sole responsibility for ensuring product quality through the life cycle of a product. Quality is ensured by collective and responsible action from each player throughout the supply chain. The roles and responsibilities of each of these players to ensure product quality are described below.

1. Role of the Raw Materials Suppliers and the Manufacturer

Raw materials suppliers are responsible for identifying manufacturing requirements and control specifications to ensure that products can consistently be produced in accordance with these requirements. A supplier must adhere to international pharmacopoeial standards, and must also conduct the necessary tests and sampling to demonstrate that a product is safe, effective for its intended use and of good quality. Additionally, a raw materials supplier must certify the safety, efficacy and stability of the finished raw materials and maintain the necessary drug master files and monographs of the active pharmaceutical ingredients.

The manufacturer is responsible for ensuring that pharmaceutical products are fit for their intended use and comply with applicable national or international standards and purchase contract specifications. It is the manufacturer's further responsibility not to place users at risk due to inadequate safety, quality or efficacy. Throughout the production process, manufacturers must adhere to Good Manufacturing Practices (GMP). As part of GMP, manufacturers should validate all raw materials and suppliers to ensure that starting materials meet production specifications. In particular, a manufacturer should have an independent quality control unit that monitors the quality of incoming materials, the quality of the product at key stages in the production process and finished products. Manufacturers also must monitor product stability to ensure that products do not deteriorate before the marked expiry date.

2. Role of the National Drug and Medical Device Regulatory Authority

The establishment of a national drug and medical device regulatory authority is an important element of a national drug policy, particularly in developing countries, since it provides the basis for product licensing which is intended to ensure the quality of both imported and domestically produced products. A comprehensive registration or licensing system should include mechanisms for independent product evaluation, including inspection and monitoring of manufacturing facilities, as well as testing and inspection of finished products. Drug regulatory authorities should have authority to recommend and enforce corrective actions when necessary.

The degree of development of drug regulatory authority varies considerably among countries, ranging from those with limited capacity (i.e., no up-to-date legislation or regulation) to those considered stringent authorities with comprehensive drug regulatory capacity (including, for example, product registration, licensing for manufacture or distribution, and a full range of quality control testing). For more about countries with stringent authorities, see Supplementary Topics, Section I: Regulatory Authorization. These differences notwithstanding, the standard of control varies from country to country and even among comparable systems. In some exporting countries, drugs are registered and sold freely but not rigorously evaluated for efficacy. In other countries, manufacturers may produce exclusively for export; the exporting country's drug regulatory authority may not closely scrutinize these manufacturing facilities. Procurement offices still need to request certificates from the drug regulatory authorities of the exporting country as recommended by the World Health Organization (WHO).

3. Role of the Logistics System

An RH programme's logistics management system plays the primary role in assisting to ensure product quality from the time the product clears customs until the time it reaches the user. The logistics system is responsible for ensuring that products are transported and stored adequately and that practices such as "First Expiry, First Out" are routinely used in distribution. Products need to be stored in such a way that their quality and integrity is preserved and that batch traceability is maintained. All logistics systems should have mechanisms for monitoring product quality upon receipt and at regular intervals during storage, and for documenting and reporting results.

4. Role of the Service Provider and End User

Service providers and users also play an important role in ensuring product quality and effectiveness. Providers should store products according to the manufacturer's directions and should check the expiry date, the integrity of the packaging and any other signs of possible deterioration of the product before distribution to users. Users should also be made familiar with the expiration date and package integrity of all products before use. Users should report any adverse reactions to the provider, who in turn should report them

to the logistics manager, clinical manager of the program or other individual depending on the nature of the complaint and the established reporting procedures.

To help the above key players better manage their processes for ensuring quality, several international standards and norms have been developed. These standards and norms establish specific procedures and practices that are designed to support a consistent approach to implementing operational activities so that inherent risks to product quality can be mitigated.

- **Good Laboratory Practices** (GLP) embody a set of principles that provide a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived.
- **Good Dispensing Practices** confirm the authenticity of the product, inspect the package and product and ensure storage of the product under required conditions.
- **The International Standards Organization** (ISO) develops standards that provide a broad umbrella for quality systems; ISO 9001 outlines criteria for a Quality Management System. ISO 13485 is a version specifically for medical devices. ISO standards also call out product specific standards such as ISO 4074 which specifies condom requirements and testing standards. However, one must be cautious when considering certification of compliance with ISO 9001 since the certification process is conducted by groups with varying levels of capacity and technical competence.
- **The CE mark** is a mandatory European marking for certain product groups to indicate conformity with the essential health and safety requirements set out in European Directives for the European Economic Area. To permit the use of a CE mark on a product, proof that the item meets the relevant requirements must be documented. Sometimes this is achieved using an external test house which evaluates the product and its documentation. Often it is achieved by company's internal self-certification process.

5. Role of the Procurement Unit

The critical role of the procurement process in obtaining quality products cannot be overemphasized. The procurement agency must be able to make certain that the products are safe and effective, and that it has maximized supplier selection and assessed its own capacity to judge these requirements. The procurement agency must maintain a comprehensive documentation infrastructure that includes policies, guidelines, norms, standards, manuals, procedures, records and related documents.

Initially, the ideal way to ensure quality products is to purchase from WHO or UNFPA pre-qualified manufacturers or from manufacturers whose products are registered by a Stringent Regulatory Authority. (For more information on pre-qualification, see Appendix VII: Prequalification). However, if this is not possible, then the purchaser is advised to take the following steps:

- *First:* Know the best available product standards. Check with the local regulatory authority to identify registered products and national standards. If these are not available, then check with other regulatory authorities or international standards bodies, such as ISO. Ensure that the products specified comply with country legislation on registration licensing status and patent registration or restrictions.
- *Second:* Know the marketplace and the available manufacturers. The purchaser must ensure that the product can be traced to the finished product manufacturer, and the manufacturer can trace the product ingredients to their producers. Understand the capacity of the supplier's plant(s). Evaluate the qualifications of key production and quality control personnel. Investigate how the supplier is regarded by knowledgeable physicians and pharmacists. Review any internationally recognized certificates that the manufacturer holds (e.g., ISO). Review any information available from public sources (such as newspapers or trade journals) concerning the supplier's performance locally or in other countries.

Check to see if the supplier is registered in an ICH or PIC/S country, if the product is registered for export only, and if the product is registered in the country of the purchaser. Contact the national regulatory authority to establish what types of inspections are performed at the manufacturing site and what medicines are quality control-tested for analytical verification of quality (levels and types of inspections, if any, can vary from country to country). Review the results of the most recent inspections and inquire about recall history. Review certification documents that are available from the regulatory agency concerning the supplier's status and compliance with current good manufacturing practices (GMP).

Buyers with pharmaceutical staff trained in GMP inspection or who hire a consultant with this expertise may perform their own inspections of manufacturers that are potential suppliers if funds are available to do this. In any case, the purchaser should always reserve the right to inspect the manufacturing facility. Request references from the supplier and check them, especially requesting any concerns or episodes of quality problems.

- *Third:* Work with the pharmacy staff to develop and articulate appropriate quality indicators and quality conformance requirements that will be used as part of the product and contract specification. One possible requirement may be to review manufacturer documents, such as batch certificates of analysis, sterility or others as applicable. Another may be to conduct pre-shipment testing by an independent, credible international laboratory (also see Module 9: Contract Performance and Monitoring). Include penalties in the contract for failure to comply with stated quality indicators.
- *Fourth:* Ensure that the product specifications are brand neutral. Beware of specifications that pertain to only one manufacturer's product.

- *Fifth:* Upon arrival of the goods, visually inspect the products to make sure that they comply with labeling and packaging requirements, and that the correct goods and quantities were received.

By implementing the above practices the Procurement Unit will help to ensure that only contraceptive products of good quality are procured and supplied to the Government of Pakistan's family planning programs.

Note: Above information provided from *Procurement Capacity Toolkit: Tools and Resources for Procurement of Reproductive Health Supplies*. PATH, 2009.

Appendix VII: Pre-qualification

This Appendix contains information about:

A. Pre-qualification Issues
B. Stringent Regulatory Authorities
C. World Health Organization Pre-qualification
D. Pre-qualification Documents

A. Pre-qualification Issues

Procuring entities sometimes choose to limit competition for contract awards to a list of potential bidders and products they have prescreened and approved through a pre-qualification process. This involves advertising the opportunity to pre-qualify and providing a set of documents to applicants that establishes rules and requirements, as well as evaluating every application. In addition, WHO's Prequalification of Medicines Programme results in a list of pre-qualified products and manufacturers. WHO's pre-qualification program is described in more detail in Section 2 of this appendix.

Pre-qualification focuses on two separate aspects of the selection process:

- Quality, safety, and efficacy of the *product.*
- Reliability of the *supplier.*

In countries with weak regulatory systems, pre-qualification can be a valuable tool for helping to ensure product quality as well as reliability of the supplier. In countries with satisfactory regulatory systems, pre-qualification tends to focus more on supplier reliability.

Pre-qualification may be an attractive time-saver in situations in which a large number of bids from questionable sources are routinely received. It may be less so for procurement that attracts bids from smaller, more regulated markets.

Curative pharmaceuticals are produced by many manufacturing firms in nearly every country in the world, and open bids can result in an excess of questionable offers. In small countries with weak regulatory systems, pre-qualification can be used to develop a core of reliable suppliers of quality products from which to draw repeatedly.

The *hormonal contraceptive* marketplace is much smaller than the general pharmaceutical marketplace, and it is dominated by products that have been licensed by stringent regulatory authorities such as those belonging to the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. In addition, WHO recently added hormonal contraceptives to its prequalification project and will soon make available on their website lists of products they have investigated

and accepted. Thus, reliability of the supplier rather than quality of the product would be the most likely focus of pre-qualification.

The *condom* marketplace is not large in comparison to general pharmaceuticals, but it has a history of quality issues. Condom production derives from a non-pharmaceutical environment, and, until the 1990s, many NRAs did not regulate or license this product. In 1989, WHO began providing guidance for condom purchasers. The most recent WHO guidance on condom procurement can be found in the document, *The Male Latex Condom: Specification and Guidelines for Condom Procurement* (2003). The United Nations Population Fund (UNFPA) employs a pre-qualification program for condom manufacturers, and procures condoms only from those manufacturers that meet the pre-qualification requirements. UNFPA is collaborating with WHO to harmonize the UNFPA pre-qualification process for condoms and intrauterine devices with WHO's pre-qualification process for medicines. Updated specifications and guidelines for procurement of these two contraceptives will be posted on the WHO and UNFPA websites upon completion. The application of solid specifications and the use of pre-qualification systems have improved the quality of condoms over the past 15 years.

RH purchasers should consider their product profiles, the availability of suppliers prequalified by WHO, the size of the marketplace and their own objectives in deciding whether or not to prequalify suppliers.

B. Stringent Regulatory Authorities

Another option available to help ensure quality products is to procure contraceptives that are approved and registered by countries with a stringent regulatory authority. A stringent regulatory authority is defined as a national regulatory authority participating in the International Conference on Harmonization (ICH) or the Pharmaceutical Inspection Convention and Co-operation Scheme (PIC/S). A description of both organizations and a list of their member countries is provided below. Limiting procurement of contraceptives from manufacturers whose contraceptives are manufactured and registered in a country belonging to one of these agencies can also serve as another method of product pre-qualification.

International Conference on Harmonization

The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a unique project that brings together the regulatory authorities and pharmaceutical industry experts of Europe, Japan and the United States to discuss scientific and technical aspects of product registration. The purpose is to make recommendations on ways to achieve greater harmonization in the interpretation and application of technical guidelines and requirements for product registration in order to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines. The objective of such harmonization is to facilitate more

economical use of human, animal and material resources; and to eliminate unnecessary delay in the global development and availability of new medicines while maintaining safeguards on quality, safety, efficacy and regulatory obligations to protect public health.

ICH Participating Regulatory Authorities (www.ich.org)

- European Union*
- Japan
- United States

* Members include: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Slovakia, Slovenia, Spain, Sweden, the Netherlands and the United Kingdom

Pharmaceutical Inspection Convention and Co-operation Scheme

The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) are two international instruments between countries and pharmaceutical inspection authorities. Together, they facilitate active and constructive cooperation in the field of GMP. PIC/S's stated mission is "to lead the international development, implementation, and maintenance of harmonized Good Manufacturing Practice (GMP) standards and quality systems of inspectorates in the field of medicinal products". This is to be achieved by developing and promoting harmonized GMP standards and guidance documents; training competent authorities, especially inspectors; assessing (and reassessing) inspectorates; and facilitating the cooperation and networking for competent authorities and international organizations.

PIC/S Participating Regulatory Authorities (www.picscheme.org)

- Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France
- Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein
- Malaysia, Netherlands, Norway, Poland, Portugal, Romania, Singapore Slovak Republic
- Spain, Sweden, Switzerland, South Africa, United Kingdom

C. World Health Organization Pre-qualification

WHO has pre-qualification programmes for vaccines, diagnostics, medical devices, and medicines. Reproductive health products are included in the medicines programme. The WHO Prequalification of Medicines Programme results in a list of prequalified products and manufacturers that comply with unified international standards. The guiding principles of the pre-qualification process require that it be:

- **Voluntary:** Manufacturers can freely choose to participate or not to participate; however, countries will be increasingly required to use the WHO pre-qualification process for procurement of donor-funded products, as it is becoming widely required

by donors such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) and other agencies within the Reproductive Health Supplies Coalition.[1]

- **Legitimate:** The general procedures and standards for pre-qualification are reviewed and approved by the WHO Expert Committee system, which includes all WHO member states and governing bodies.
- **Endorsement:** The pre-qualification system was presented to and supported by the 10th and 11th International Conference of Drug Regulatory Authorities (ICDRA) meetings in 2002 and 2004. ICDRA is a forum for drug regulatory authorities of WHO member states that strengthens collaboration and identifies priorities for the regulation of medicines.
- **Transparent:** All information from the pre-qualification process is available on the WHO pre-qualification website. The pre-qualification process for medicines and devices is open to both innovator (patented) products and generic products. For pre-qualification to work, there must be multiple manufacturers participating. The WHO Pre-qualification Programme is efficient in recognizing that some medicines have been through rigorous regulatory testing by credible agencies.
- **Capacity-strengthening:** The pre-qualification process helps manufacturers strengthen capacity. If a manufacturer does not initially meet standards, it receives a specific report of findings and recommendations for improvements. Pre-qualification is not a strict pass/fail process. Manufacturers can make improvements and correct deficiencies and then resubmit and continue to pursue pre-qualification.

Roles and responsibilities in the WHO pre-qualification process are divided as follows:

- WHO provides technical support, scientific support and a guarantee that international norms and standards are incorporated and adhered to throughout the entire pre-qualification process (including assessment, inspection and quality control).
- For medicines, the assessment of dossiers and inspection of manufacturing sites are primarily done by qualified personnel appointed by WHO from the national regulatory authorities of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S, http://www.picscheme.org) and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH, http://www.ich.org) member countries. (See Section I: Product Inspection and Testing and Section K: Regulatory Authorities for more information on the PIC/S and ICH.) WHO also arranges for site

[1] The Reproductive Health Supplies Coalition is a global partnership of public, private and non-governmental organizations dedicated to ensuring that all people in low- and middle-income countries can access and use affordable, high-quality supplies to ensure their better reproductive health. For more information, see http://www.rhsupplies.org/.

inspection of manufacturers to assess compliance with current good manufacturing practices (cGMPs). A representative of the national regulatory authority traditionally accompanies the inspection team for the site inspection.

- Condom and intrauterine device pre-qualification is overseen and implemented by the United Nations Population Fund on behalf of WHO and is supported by independent technical experts with in-depth knowledge and expertise in the manufacturing and quality assurance (QA) issues related to these products.

WHO pre-qualification systems cover these QA activities:

- Development, establishment and promotion of norms and international standards to ensure safety and QA for products.
- Assistance to countries in building national regulatory capacity through networking, training and information sharing.
- Provision of expertise and technical assistance through various activities in the areas of QA, regulation and legislation, safety and efficacy.
- Provision of guidance in regulation, safety and QA.
- Assessment of data from manufacturers regarding the quality, safety and efficacy of their products, including details about the purity of all ingredients used in manufacturing, data about finished products (such as information about stability) and the results of in vivo bioequivalence tests (clinical trials conducted in healthy volunteers).
- Performance of inspections at the manufacturing sites and assessment of working procedures for compliance with WHO cGMPs.
- Shipment of products to professional control testing laboratories for analytical verification of quality.
- Re-qualification of all medicines after 1 to 3 years and at a minimum every 5 years.
- Performance of random quality control testing of pre-qualified medicines that have been supplied to countries.
- Investigation and resolution of complaints.
- Monitoring of supplier quality and taking corrective action if standards are not maintained.

D. Pre-qualification Documents

Two different sets of pre-qualification documents available on organizational websites are listed in Section I.3. One focuses on product quality, the other on supplier reliability.

- ***Quality focus:*** *Practical Guidelines on Pharmaceutical Procurement for Countries with Small Procurement Agencies*; *Attachment 1: Model Questionnaire for Pre-qualification of Suppliers* (WHO Regional Office for the Western Pacific, 2002) (Section I.3.b).
- ***Reliability focus:*** *Standard Prequalification Document: Procurement of Health Sector Goods*, Trial Edition (World Bank, 2002) (Section I.3.a).[2]

[2] Also see the "Bidder Information Form" in the World Bank's Standard Bidding Document: Procurement of Health Sector Goods.

Appendix VIII: Pre-Shipment Compliance Programmes

This Appendix contains information about:

A. Pre-Shipment Compliance Programmes - General
B. Sample Compliance Programme (OCs, Injectables)
C. Sample Inspection Order
D. Visual Inspection Review Guidelines
E. ISO 2859-1 – Relevant Tables

A. Pre-Shipment Compliance Programmes - General

Pre-shipment compliance programmes are used to assure the purchaser that goods made ready for shipment by the seller will meet all expectations of quality and safety as well as other contractual requirements. Used in conjunction with a Letter of Credit, they are an especially effective means of contract enforcement since payment can be withheld until the seller presents documentary proof of compliance to a designated bank.

Pre-shipment compliance programmes involve inspection of the product at the manufacturer's facility before shipment. They may be limited to visual examination of the products, packaging, packing, labelling and markings and quality assurance documents or, they may include drawing samples and sending them out for laboratory testing by an independent third party to verify quality, formulation, strength, dimensions and other characteristics.

Different products and different situations call for different levels of pre-shipment compliance activity, and in some instances, none at all. Pharmaceutical products (including oral and injectable contraceptives) and IUDs purchased directly from well-known, reputable manufacturers in industrialized countries (US, EU, Japan, Canada, Australia, Switzerland, etc.) generally do not require this additional assurance of quality because they are licensed and monitored under the auspices of very strong National Regulatory Authorities. However, manufacturers can be requested to provide appropriate certification of laboratory testing.

Condoms are a different case. They are not regulated by pharmaceutical codes, but as medical devices, and then, not in all cases. The manufacture of condoms is complex and can be influenced by a variety of different manufacturing and raw material factors – including seasonal weather patterns at the plantation where the latex raw material originated and dust in the manufacturing facility. Even when manufactured under a strict quality management system, there is no guarantee of a uniformly high-quality product: a small number of condoms in any lot may be defective and there is always a risk that quality may vary

between production runs. When condoms are not manufactured under strict quality control, the risk of poor quality product increases dramatically. In addition, unscrupulous manufacturers have been known to manipulate the sensitivity of their "100% electronic testing" equipment. Thus, for the purchaser, stringent pre-shipment compliance procedures are necessary. WHO has published a set of specifications and guidelines[1] for condom procurement designed to help "ensure the highest level of safety consistent with high volume purchases, the needs of different populations, harsh environmental conditions and the probability of less than ideal storage conditions". These specifications and guidelines include a detailed pre-shipment compliance programme of inspection and testing.

In summary, condoms always require pre-shipment inspection and testing, regardless of their origin; pharmaceuticals (including oral and injectable contraceptives) and IUDs require a pre-shipment compliance assessment if they originate in countries other than those with strong, recognized National Regulatory Authorities such as US, EU, Japan, Canada, Australia, Switzerland, etc.

The recommended content of a pre-shipment compliance programme varies according to the product, with condoms requiring the most stringent examination:

Condoms	Inspection, sampling and testing of an entire statistical sample1 from each manufacturing lot. (usually 200 –315 samples)
Oral Contraceptives	Inspection and sampling of each manufacturing lot; review of the manufacturer's quality certification; testing of 5 samples from each lot for first three shipments from each manufacturer.
Injectable Contraceptives	Same procedure as oral contraceptives except the number of samples for testing should be increased to 20.
IUDs	Same procedure as oral contraceptives except testing should be done on the entire statistical sample. The number of samples depends on the lot size (50 – 100 samples is a reasonable estimate). A specialized laboratory is required. IUD's are medical devices, but regulated as drugs in some cases because of bioactive copper content. Dimensionality, flexibility, copper purity and the quality/chemistry of polyethylene raw material are all issues.

1. Inspection

Inspection criteria must outline exactly what is to be examined and what constitutes compliance. The Sample Inspection Order provided at the end of Module V and the copy located at Letter B of this Appendix (IV) may be modified and used for inspection of packing, marking and documentation of any product. In addition to a visual scrutiny of the product, packing and marking, it directs the inspector to examine documentation of the manufacturer's test results to confirm that values for the lot(s) prepared for shipment are within the range mentioned in the product's National Regulatory Authority (NRA) dossier and/or specified in the relevant pharmacopoeia or standard. In the case of condoms, the procuring entity should refer to the WHO specification and guideline.

[1] The Male Latex Condom – Specification and Guidelines for Condom Procurement

In cases where testing will be required, the procuring entity should add an instruction for the inspector to prepare the required number of samples and transmit them to a specified laboratory.

Pre-shipment inspection of the documentation and physical characteristics of most consignments typically costs under $1,000. However, rates vary and are usually based on the inspector's time and travel distance, so firm quotations should be obtained.

The following organizations offer pre-shipment inspection and sampling services:

Partial List of International Inspection Agents	
FRANCE Bureau Veritas 67/71, boulevard du Château - 92200 Neuilly-sur-Seine - France Tel: +33 (0) 1 55 24 70 00 Fax: +33 (0) 1 55 24 70 01	SWITZERLAND Societe Generale de Surveillance SA Consumer Products Department 1, Place des Alps CH-1211 Geneva 1, Switzerland Tel. +41-22-739 9111 Fax. +41-22-731 1666
UNITED KINGDOM Crown Agents St Nicholas House, St Nicholas Road Sutton, Surrey SM1 1EL United Kingdom Tel. +44 (020) 8643 3311 Fax. +44 (020) 8643 8232 www.crownagents.com	UNITED KINGDOM Intertek Group plc 25 Savile RowLondon Greater London W1S 2ES United Kingdom Tel. +44 20 7396 3400

2. Sampling

Compliance activities are often based on a "sampling" of the product rather than 100 percent inspection. For purposes of this manual, "sampling" is defined as the process of selecting a small, representative quantity from a much larger batch or consignment of products.

Inspecting a representative sample from a large body of goods enables judgment about the quality of the entire batch or consignment without having to look at each individual unit. However, there is no guarantee that a randomly selected sample will indeed represent the population from which it comes, so steps must be taken to improve its reliability. Statistical sampling plans such as ISO 2859 help to provide necessary assurances. ISO 2859 is discussed further below with selected pages appearing as Section E of this Appendix (IV). Readers seeking additional explanation should refer to *Chapter One- Essential Elements of Condom Quality Assurance* in the WHO Model Condom Specification.

Sampling should be done by an independent sampling organization or the laboratory contracted for testing, and not by the factory producing the product, for obvious reasons. Samples, once taken, must be sealed and dispatched under the sampler's supervision.

ISO 2859 - Statistical Sampling

Statistical evaluations are made according to International Organization for Standardization Sampling Procedures and Tables for Inspection by Attributes (ISO 2859-1). Relevant ISO 2859 tables are located in Section E of this Appendix (IV). Please refer to them as you read the following explanation of their use:

Table I is used to establish a Sample Size Code Letter based on the lot size (total number of units to be represented by the test result) and the level of inspection (single, double; normal, tightened, reduced, etc.) deemed appropriate for the situation and the specific attribute.[2] Inspection levels are indicated in the product specification that appears in the bidding and contract documents.

The column in Table I titled "Lot or Batch Size" shows the number of units that make up the lot. For example, in a lot formed by 10,000 units, a sample corresponding to the letter "L" would be drawn if a general inspection level (II) were to be applied.

Table I also is used to establish the number of multiple unit boxes from which to draw the sample products. For example, if the 10,000 units were packed in 100 multiple unit boxes, according to Level II, the sample of "L" units should be taken from a number of multiple boxes corresponding to letter "F".

Tables II and III show the actual number of samples (sample size) to be drawn and the number of non-conformers allowed (AQL – Acceptance Quality Limit). A sample size corresponding to each code letter is shown in the adjacent "Sample Size" column.

To know what sample size corresponds to the code letters L and F in the example given above, Table IIA (Single Sampling Plan, Normal Inspection) or Table IIIA (Double Sampling Plan, Normal Inspection) should be consulted depending upon which type of sampling plan is designated for the test. The corresponding values on Table IIA are 200 for code letter L and 20 for code letter F. This means that for a lot or batch of 100 multiple boxes, 20 would be chosen, out of which a proportionate number of units would be taken to gather the 200 that should make up the sample for inspection. The sample should be taken from the multiple boxes at random.

Inspection Level Recommendations

In the case of a new supplier or a manufacturer just beginning operations, the first five lots should be inspected at a TIGHTENED level using Table IIB (Single

[2] The WHO model condom specification uses G-1 for performance requirements, S-2 for design requirements and S-3 for packaging requirements.

Plan, Tightened Inspection) or Table IIIB (Double Plan, Tightened Inspection) as designated for the tests. If the first five lots are consecutively approved, switch to a NORMAL inspection (less strict) level (Tables IIA or IIIA).

NORMAL inspection can be changed to REDUCED (less strict) level (Tables IIC or IIIC) if the following requirements are met:

Satisfactory results from the original inspection of the last 10 lots received.

The total number of defective units found in those 10 lots is the same or smaller than the number indicated on Table VIII (Limit Numbers for Reduced Inspection). If multiple or double sampling plans are used, the results of the total number of samples will be considered, not just the ones corresponding to the first sampling.

NORMAL Level Inspection (Tables IIA or IIIA) should be changed to TIGHTENED (more strict) level (Tables IIB or IIIB) when two out of five consecutive lots have been rejected in the original inspection.

When TIGHTENED inspection is in effect, NORMAL inspection can be instituted after five consecutive lots or batches have been considered acceptable on original inspection. If 10 consecutive production lots remain on TIGHTENED inspection, then production should be stopped until problems have been resolved.

RESUBMITTED LOTS OR BATCHES. Lots or batches found unacceptable must be resubmitted for inspection only after all units are re-examined or retested and all defective units are removed or defects corrected. The responsible authority must determine whether normal or tightened inspection will be used, and whether re-inspection will include all types or classes of defects or particular types or classes of defects that caused initial rejection.

3. Testing

If laboratory testing is included in the pre-shipment compliance programme, the inspection agent should be directed to randomly select a pre-determined number of samples from each manufacturing lot and forward them to a designated laboratory. Condom testing involves a relatively large sample size while pharmaceutical product testing (including oral and injectable contraceptives) normally requires only a small sample. For any typical batch of products supplied by a reputable manufacturer, one set of samples is sufficient for analytical tests. If any possibility exists that samples are deteriorated or adulterated, at least one additional set of samples should be available for confirmation of test results. Cost is dependent upon the product and the tests required.

In order to avoid charges and counter charges of prejudice (e.g. disputed results), testing should be done by an independent accredited laboratory, and not by the purchaser's or the supplier's personnel and laboratories.

Classification of Defects and Acceptable Quality Levels (AQL)

Purchasers are responsible for setting limits on the maximum percentage of defects they will accept. Defects are classified as critical, major or minor for purposes of assigning acceptance quality levels (AQLs).

Critical defect	A defect which, according to experience and professional criteria, makes the product dangerous or not viable for its intended use.
Major defect	A defect that is unlikely to reduce usability and may make product use more difficult, but does not have the safety and efficacy risk associated with a critical defect.
Minor defect	A defect that is unlikely to affect usability of the product but represents a departure from the specifications.

The quality of a batch of products is not just about the item itself - pills injectables, condoms, etc.- but also about the packaging and packing that protect the product from deterioration and about markings necessary for safe storage and use. "Shipping cartons" contain "inner boxes," which, in turn, contain individual "units" or "packages". Thus, three levels of packaging contribute to the overall quality of a product.

For important performance and safety properties, the AQL should be set very low, zero for critical defects in the case of pharmaceutical products and IUDs. For properties that are less important and do not affect the performance, slightly higher limits are often set: 1% for major defects; 4% for minor defects. In the case of condoms, the WHO guideline specifies AQL levels for different properties ranging from 0.25 and 0.4 at the critical level through AQL 1, 1.5 and 2.5 at the major level and 4.0 at the minor level.

Sample Compliance Programme

Section B of this Appendix (IV) contains a *Sample Compliance Programme* with wording that is appropriate for inclusion in bidding documents and specifications for oral or injectable contraceptives. It may be adapted for procurement of IUDs as well. For condoms, the reader should refer to the *WHO Guideline and Model Specification for Condom Procurement.*

Visual Inspection Review Guidelines for OCs, Injectable Contraceptives and IUDs are included at the end of this Appendix (IV) for additional reference.

B. Sample Compliance Programme (OCs, Injectables)

Prior to shipment, the Purchaser, or his appointed representative, has the right to sample and inspect each consignment of [oral] [injectable] contraceptives at the factory or Supplier's warehouse in accordance with ISO 2859 Inspection by Attributes and Technical Specification _____ of this contract.

1. Packaging, Packing and Marking

One hundred percent (100%) of the exterior shipping cartons will be examined for:

i. General physical characteristics and condition

ii. Markings per Technical Specification _____

A representative sample of the inner boxes will be drawn from the exterior shipping cartons at General Inspection Level II, or at the discretion of the Purchaser, General Inspection Level III, Single Sampling Plan for Normal Inspection.

The sample will be examined for:

i. General physical characteristics per Technical Specification _____

ii. Markings per Technical Specification _____

All aspects of the samples, including the exterior shipping cartons, inner boxes and primary packaging will be further inspected and any defects classified as follows:

Critical

- The shipping documents do not coincide with information on the primary package
- Damage to the primary package[3] or its contents
- Illegible or missing text or markings on the primary package
- Batch/lot number or expiration date incorrect or missing from labelling
- Product information sheet does not match the product
- Package insert or information sheet missing
- Shipping carton badly closed or broken
- Inner boxes in bad condition, open, dirty or torn/broken
- Individual boxes missing from the multiple-unit shipping cartons
- Batch/lot number or expiration date incorrect or missing from inner boxes
- Foreign matter in inner boxes

Major

- Manufacturer's national registration number missing on inner boxes
- Goods missing from the inner boxes
- Manufacturer's name, address, or importing country's registration number missing from inner boxes
- Package insert or information sheet illegible, dirty or torn
- Labelling missing from inner boxes
- Instructions for storage missing from inner boxes

[3] Blister pack, ampoule.

Minor

- Printing on primary package defective but legible

For critical defects, the acceptable quality level (AQL) shall be 0 (zero) percent; for major defects, the AQL shall be 1 percent; for minor defects, the AQL shall be 4 percent.

2. Tablet/Ampoule

At the discretion of the Purchaser, all or part of the sample may be sent to a qualified independent laboratory to confirm any or all of the manufacturer's test data on the final product. [for OC's only: In addition, a package seal integrity test must be performed.]

A Certificate of Analysis for production lot(s) represented by test samples shall be made available to the inspector and/or Purchaser upon request. The certificate shall state all tests performed, their specifications and the actual test results obtained. In each case, test results shall meet pharmacopoeia limits.

3. Resolution of Defects

a. Packaging, Packing and Markings

- Defects in exterior shipping carton markings must be corrected by the Supplier prior to shipment.
- All Critical Defects must be corrected and re-inspected at the Supplier's expense or all products from the same production lot will be rejected.
- Major Defects must be corrected by the Supplier to the satisfaction of the Purchaser prior to shipment.
- Minor Defects will be resolved on a case-by-case basis to the satisfaction of the Purchaser.

b. Product

- Any deviation from the manufacturer's Certificate of Analysis, product specification or Pharmacopoeia limits shall result in rejection of the entire production lot.

C. Sample Inspection Order (copy of Exhibit 51)

To: _____(*insert name of inspection agent/company*)

Date:

Contract Number:

Vendor: XYZ Corporation

Consignee: MOH, Government of Pakistan

INSPECTION ORDER

Inspect packing and marking for compliance with section _____ of attached technical specifications.

Inspection shall be conducted in accordance with ISO 2859-1, Inspection by Attributes

Inspection level shall be S-3 with an AQL of 2.5%:

For exterior shipping cartons, the lot size shall be the number of exterior shipping cartons and the sample unit shall be one exterior shipping carton

For other levels of packing, the lot size shall be the number of inner boxes and the sample unit shall be one inner box.

1. Inspect and score for defects as follows

	Defects*
Contents	Quantity of goods not as specified; packets or strips not as specified
Marking	Omitted; incorrect; illegible' of an improper size, location, sequence, or method of application
Materials	Packaging/packing materials not as specified, missing, damaged, or not serviceable
Workmanship	Shipping cartons inadequately closed and secured; poor application of internal packaging and packing material; distorted inner boxes

* Examination of defects of closure shall be performed on units fully prepared for delivery.

a. Exterior shipping cartons selected at random from lot proposed for delivery.

b. Inner boxes selected at random from sample shipping cartons.

2. Examine Documentation

a. Refer to attached Shipping Instructions and confirm all documents listed are complete.

b. Confirm that values appearing on Certificates of Analysis for the lot(s) prepared for shipment are within the range mentioned in the product's National Regulatory Authority (NRA) dossier and/or specified in the relevant pharmacopoeia per the procurement specification.

3. **Provide a written report for approval by the Government of Pakistan on packing and marking and documentation prior to release of a clean bill of goods.**
4. **Unless otherwise specified in writing, the inspection agent is not authorized to sign the "Authorization for Shipment" form.**

D. Visual Inspection Review Guidelines

Visual Inspection Review Guidelines
Oral Contraceptives

Oral contraceptives come in cycles of 21 or 28 tablets. In the 28-day cycles, seven placebo or iron tablets are provided in addition to the contraceptive tablets. Iron tablets generally are larger and brown in colour. Most oral contraceptives are packaged in blister packages with a cardboard overpack. Frequently, three cycles are packaged together in a sealed foil overpack. Oral contraceptive shelf life ranges from three to five years at 37° C although the majority of brands have a five-year shelf life. Blister packaging provides good protection from adverse environmental conditions.

The labelling criteria listed below are comprehensive and useful not just in identifying the product, but in managing it successfully within the logistics system. However, not all contraceptives are procured with such extensive labelling specifications. If any of the labelling criteria listed below are not applicable, mark the appropriate box in the n/a column. Product procurement specifications should be consulted prior to finalizing the inspection criteria.

Date: _____	Receipt Report Number: _____
Product: _____	Lot Number: _____
Brand Name: _____	Manufacturer: _____
Expiration Date: _____	Date of Manufacture: _____
Inspection Lot Size: _____	Sample Size: _____
Warehouse Location: _____	Second Sample Size: _____
_____	
_____	

VISUAL INSPECTION CRITERIA	MEETS CRITERIA			DEFECT CLASSIFICATION
SHIPPING CARTONS Examine 100 percent of the shipping cartons against the shipping documents.				
Inspection criteria				
Carton labelling:	Yes	No	n/a	
Product/brand name	☐	☐	☐	Major
Lot/batch number	☐	☐	☐	Major
Expiration date	☐	☐	☐	Major
Manufacturer's name, address	☐	☐	☐	Minor
Date of manufacture	☐	☐	☐	Minor
Contents and quantity	☐	☐	☐	Minor
Drug registration number	☐	☐	☐	Minor
Storage instructions	☐	☐	☐	Minor
Carton condition/content:				
Carton in good condition, undamaged	☐	☐		Major
All inner boxes present, none missing	☐	☐		Major
Proper flap/closure	☐	☐		Minor

Oral Contraceptives (continued)

VISUAL INSPECTION CRITERIA	MEETS CRITERIA			DEFECT CLASSIFICATION
INNER BOXES				
Inspection criteria				
Inner box labelling:	Yes	No	n/a	
Product/brand name	☐	☐	☐	Critical
Lot/batch number	☐	☐	☐	Critical
Expiration date	☐	☐	☐	Critical
Date of manufacture	☐	☐	☐	Minor
Manufacturer's name, address	☐	☐	☐	Minor
Contents and quantity	☐	☐	☐	Minor
Drug registration number	☐	☐	☐	Minor
Storage instructions	☐	☐	☐	Minor
Inner box condition/content:				
Inner box in good condition (undamaged, unopened)	☐	☐		Major
All unit packages present, none missing	☐	☐		Major
Inner box contains no foreign matter	☐	☐		Minor
UNIT PACKAGES				
Inspection criteria				
Unit package llabelling:				
Product/brand name	☐	☐	☐	Critical
Lot/batch number	☐	☐	☐	Critical
Expiration date	☐	☐	☐	Critical
Date of manufacture	☐	☐	☐	Critical
Manufacturer's name, address	☐	☐	☐	Critical
Product use instructions	☐	☐	☐	Critical
Arrow indicating sequence of pills	☐	☐	☐	Critical
Contents and quantity	☐	☐	☐	Major
Drug registration number	☐	☐	☐	Major
Storage instructions	☐	☐	☐	Minor
Print on unit package is legible	☐	☐	☐	Minor
Product use instructions properly folded	☐	☐	☐	Minor
Unit package condition/content:				
Unit package in good condition (undamaged, unopened)	☐	☐		Critical
Pills in good condition (unbroken, correct color, none missing)	☐	☐		Critical
Good package seal, no breaks	☐	☐		Critical
Unit package contains no foreign matter	☐	☐		Critical

Visual Inspection Review Guidelines for Injectable Contraceptives

Injectable contraceptives are available in several formulations, including oil-based and aqueous suspension and dosage forms. Contraceptive protection per dose ranges from one month to three months depending upon the product. Injectables are available in pre-filled syringes, but are most commonly provided in single- or multi-dose vials or ampoules with disposable syringes. Shelf life for injectable contraceptives ranges from two to five years depending upon the formulation. Recommended storage temperature generally is 15-30° C. Storage temperature is critical to product stability; oil-based solutions become rancid at elevated temperatures. Manufacturers' recommended storage conditions should be followed.

The labelling criteria listed below are comprehensive and useful not just in identifying the product, but in managing it successfully within the logistics system. Not all contraceptives are procured with such extensive labeling specifications, however. If any of the labelling criteria listed below are not applicable, mark the appropriate box in the n/a column. Product procurement specifications should be consulted prior to finalizing the inspection criteria.

Date: _____	Receipt Report Number: _____
Product: _____	Lot Number: _____
Brand Name: _____	Manufacturer: _____
Expiration Date: _____	Date of Manufacturer: _____
Inspection Lot Size: _____	Sample Size: _____
Warehouse Location: _____	Second Sample Size: _____
_____	
_____	

VISUAL INSPECTION CRITERIA	MEETS CRITERIA			DEFECT CLASSIFICATION
SHIPPING CARTONS Examine 100 percent of the shipping cartons against the shipping documents. Inspection criteria				
Carton labelling:	Yes	No	n/a	
Product/brand name	☐	☐	☐	Major
Lot/batch number	☐	☐	☐	Major
Expiration date	☐	☐	☐	Major
Manufacturer's name, address	☐	☐	☐	Minor
Date of manufacture	☐	☐	☐	Minor
Contents and quantity	☐	☐	☐	Minor
Drug registration number	☐	☐	☐	Minor
Storage instructions	☐	☐	☐	Minor
Carton condition/content:				
Carton in good condition, undamaged	☐	☐		Major
All inner boxes present, none missing	☐	☐		Major
Proper flap/closure	☐	☐		Minor

Injectable Contraceptives (continued)

VISUAL INSPECTION CRITERIA	MEETS CRITERIA			DEFECT CLASSIFICATION
INNER BOXES				
Inspection criteria				
Inner box labelling:	Yes	No	n/a	
Product/brand name	☐	☐	☐	Critical
Lot/batch number	☐	☐	☐	Critical
Expiration date	☐	☐	☐	Critical
Date of manufacture	☐	☐	☐	Minor
Manufacturer's name, address	☐	☐	☐	Minor
Contents and quantity	☐	☐	☐	Minor
Drug registration number	☐	☐	☐	Minor
Storage instructions	☐	☐	☐	Minor
Inner box condition/content:				
Inner box in good condition (undamaged, unopened)	☐	☐		Major
All unit packages present, none missing	☐	☐		Major
Inner box contains no foreign matter	☐	☐		Minor
UNIT PACKAGES				
Inspection criteria				
Unit package labelling:				
Product/brand name	☐	☐	☐	Critical
Lot/batch number	☐	☐	☐	Critical
Expiration date	☐	☐	☐	Critical
Date of manufacture	☐	☐	☐	Critical
Product use instructions	☐	☐	☐	Critical
Dosage	☐	☐	☐	Critical
Manufacturer's name, address	☐	☐	☐	Critical
Contents and quantity of doses	☐	☐	☐	Major
Drug registration number	☐	☐	☐	Major
Storage instructions	☐	☐	☐	Minor
Unit package condition/content:				
Glass vial or ampoule in good condition (undamaged, unopened)	☐	☐		Critical
Vial or ampoule free of foreign matter	☐	☐		Critical
Vial or ampoule free of leakage	☐	☐		Critical
Vial or ampoule free of solid material or caking	☐	☐		Critical
Correct colour	☐	☐		Critical
Sufficient number of syringes for contraceptive doses	☐	☐		Critical
Good vial seal, no breaks	☐	☐		Critical

Visual Inspection Review Guidelines
Intrauterine Devices

IUDs come in a variety of designs. The majority of IUDs in use today have a frame of molded plastic with some form of copper attached. The shelf life for IUDs currently ranges from three to seven years.

The labelling criteria listed below are comprehensive and useful not just in identifying the product, but in managing it successfully within the logistics system. However, not all contraceptives are procured with such extensive labelling specifications. If any of the labelling criteria listed below are not applicable, mark the appropriate box in the n/a column. Product procurement specifications should be consulted prior to finalizing the inspection criteria.

Date: _____
Product: _____
Brand Name: _____
Expiration Date: _____
Inspection Lot Size: _____
Warehouse Location: _____
_____
_____

Receipt Report Number: _____
Lot Number: _____
Manufacturer: _____
Date of Manufacturer: _____
Sample Size: _____
Second Sample Size: _____

VISUAL INSPECTION CRITERIA	MEETS CRITERIA			DEFECT CLASSIFICATION
SHIPPING CARTONS Examine 100 percent of the shipping cartons against the shipping documents.				
Inspection criteria				
Carton labelling:	Yes	No	n/a	
Product/brand name	☐	☐	☐	Major
Lot/batch number	☐	☐	☐	Major
Expiration date	☐	☐	☐	Major
Manufacturer's name, address	☐	☐	☐	Minor
Date of manufacture	☐	☐	☐	Minor
Contents and quantity	☐	☐	☐	Minor
Drug or device registration number	☐	☐	☐	Minor
Storage instructions	☐	☐	☐	Minor
Carton condition/content:				
Carton in good condition, undamaged	☐	☐		Major
All inner boxes present, none missing	☐	☐		Major
Proper flap/closure	☐	☐		Minor
INNER BOXES				
Inspection criteria				
Inner box labelling:				
Product/brand name	☐	☐	☐	Critical
Lot/batch number	☐	☐	☐	Critical
Expiration date	☐	☐	☐	Critical
Manufacturer's name, address	☐	☐	☐	Minor

Intrauterine Devices (continued)

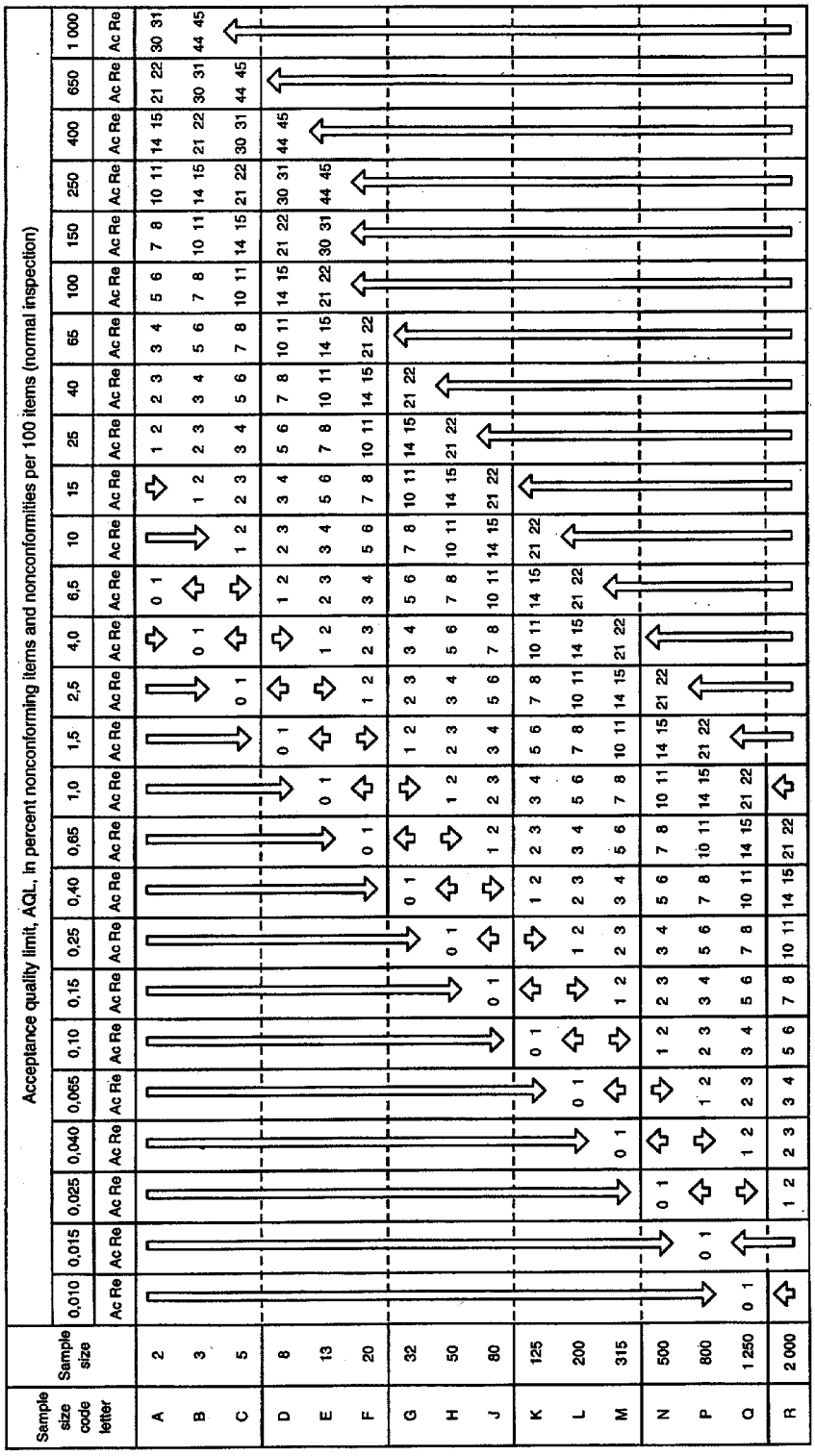
VISUAL INSPECTION CRITERIA	MEETS CRITERIA			CLASSIFICATION OF DEFECTS
	Yes	No	n/a	
Date of manufacture	☐	☐	☐	Minor
Contents and quantity	☐	☐	☐	Minor
Drug or device registration number	☐	☐	☐	Minor
Storage instructions	☐	☐	☐	Minor
Inner box condition/content:				
Inner box in good condition (undamaged, unopened)	☐	☐		Major
All unit packages present, none missing	☐	☐		Major
Inner box contains no foreign matter	☐	☐		Minor
UNIT PACKAGES				
Inspection criteria				
Unit package labelling:				
Product/brand name	☐	☐	☐	Critical
Lot/batch number	☐	☐	☐	Critical
Expiration date	☐	☐	☐	Critical
Date of manufacture	☐	☐	☐	Critical
Manufacturer's name, address	☐	☐	☐	Critical
Product information card within sterile package	☐	☐	☐	Critical
Product use instructions	☐	☐	☐	Critical
Contents and quantity	☐	☐	☐	Major
Drug or device registration number	☐	☐	☐	Major
Print on insert card or use instructions is legible	☐	☐	☐	Minor
Unit package condition/content:				
Unit package in good condition (undamaged, unopened)	☐	☐		Critical
All components present, none missing (inserter tube, flange, IUD, tail, copper components if relevant, inserter rod, insert card, or information)	☐	☐		Critical
Components in good condition, not misshapen	☐	☐		Critical
Good package seal, no breaks	☐	☐		Critical
Unit package contains no foreign matter	☐	☐		Critical

E. ISO 2859-1 Relevant Tables

Table 1 - Sample size code letters (see 10.1 and 10.2)

Lot size	Special inspection levels				General inspection levels		
	S-1	S-2	S-3	S-4	I	II	III
2 to 8	A	A	A	A	A	A	B
9 to 15	A	A	A	A	A	B	C
16 to 25	A	A	B	B	B	C	D
26 to 50	A	B	B	C	C	D	E
51 to 90	B	B	C	C	C	E	F
91 to 150	B	B	C	D	D	F	G
151 to 280	B	C	D	E	E	G	H
281 to 500	B	C	D	E	F	H	J
501 to 1 200	C	C	E	F	G	J	K
1 201 to 3 200	C	D	E	G	H	K	L
3 201 to 10 000	C	D	F	G	J	L	M
10 001 to 35 000	C	D	F	H	K	M	N
35 001 to 150 000	D	E	G	J	L	N	P
150 001 to 500 000	D	E	G	J	M	P	Q
500 001 and over	D	E	H	K	N	Q	R

Table 2-A — Single sampling plans for normal inspection (Master table)



⇩ = Use the first sampling plan below the arrow. If sample size equals, or exceeds, lot size, carry out 100 % inspection.

⇧ = Use the first sampling plan above the arrow.

Ac = Acceptance number

Re = Rejection number

Table 2-B — Single sampling plans for tightened inspection (Master table)

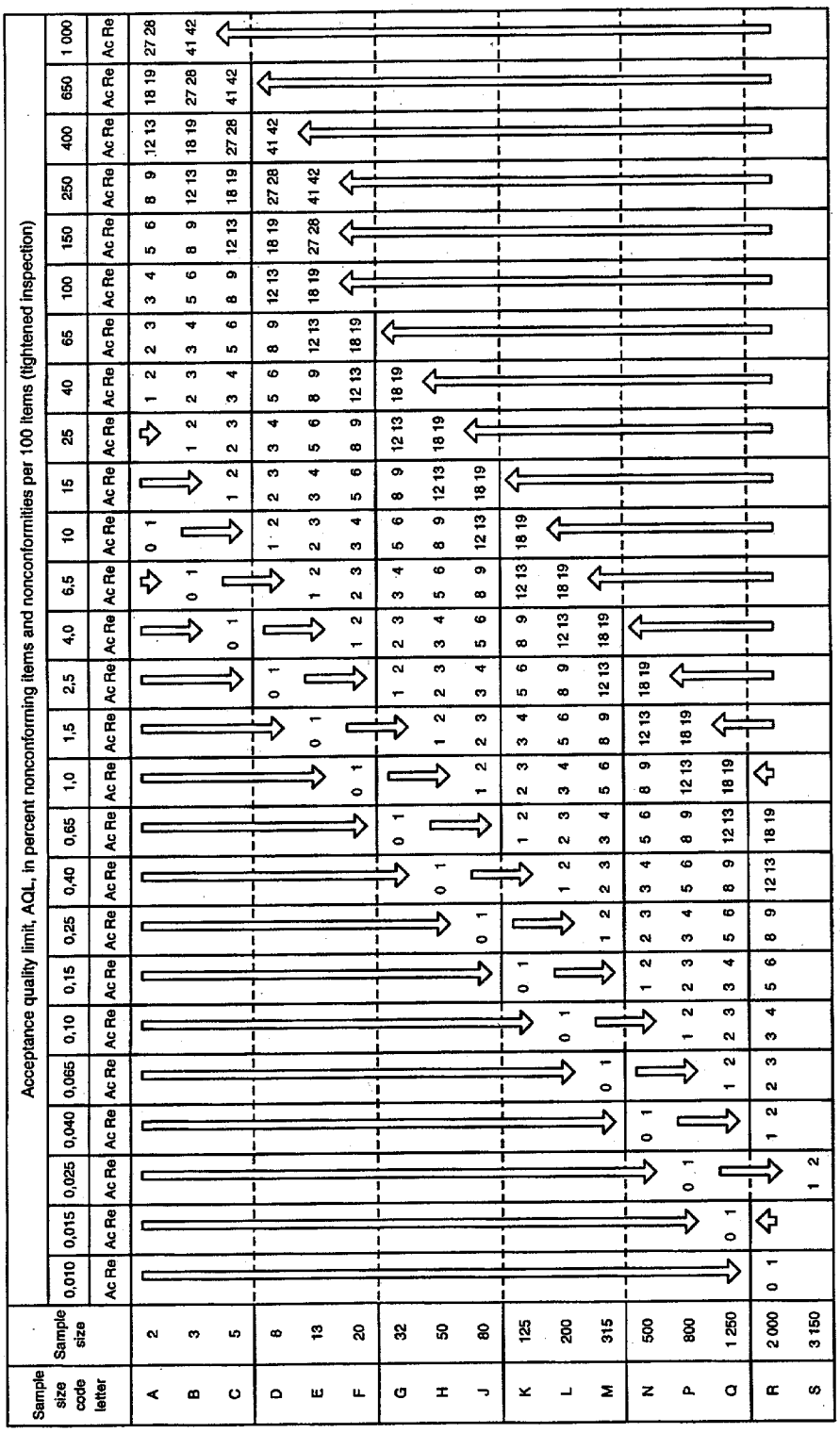


Table 2-C — Single sampling plans for reduced inspection (Master table)

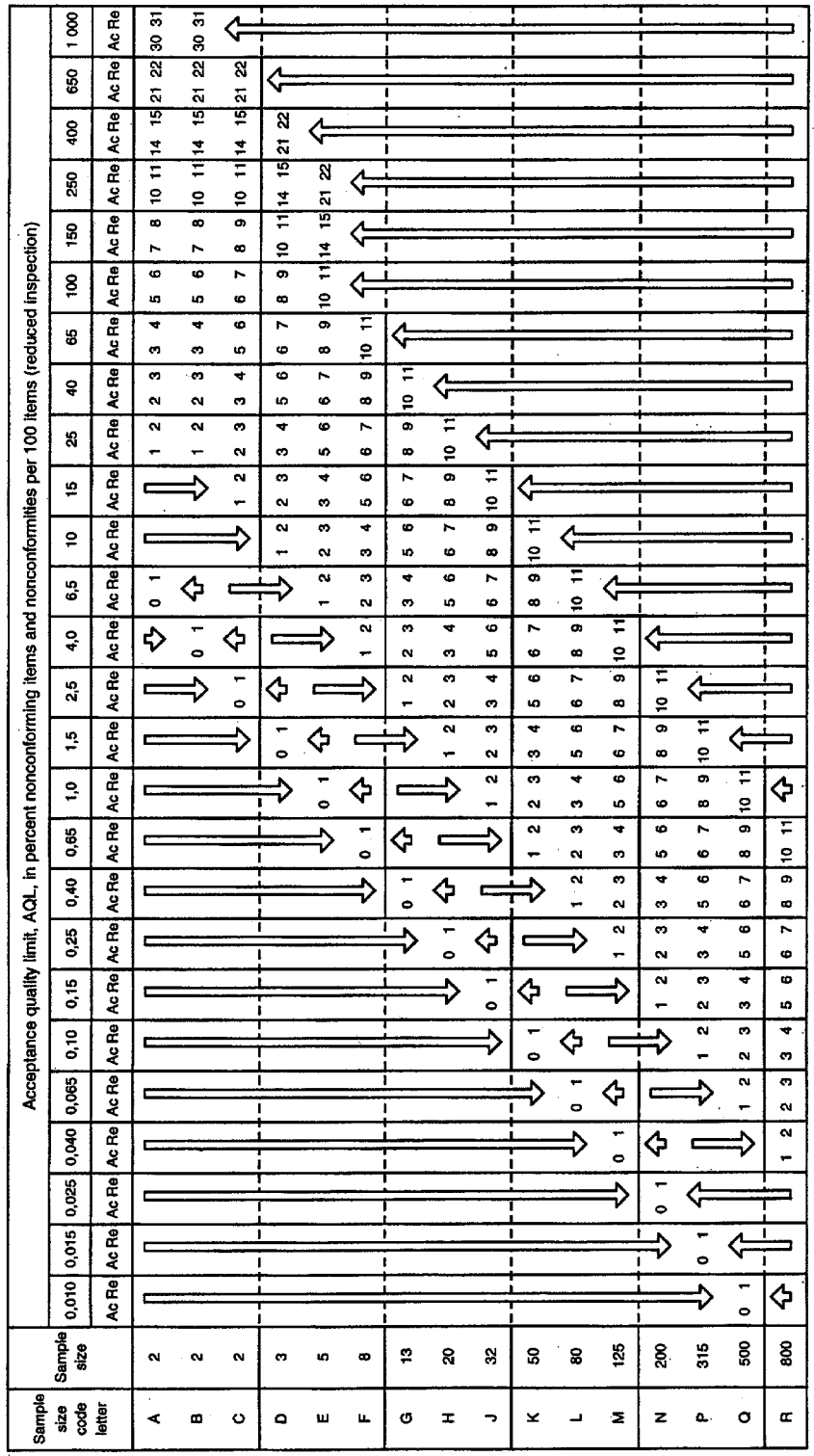
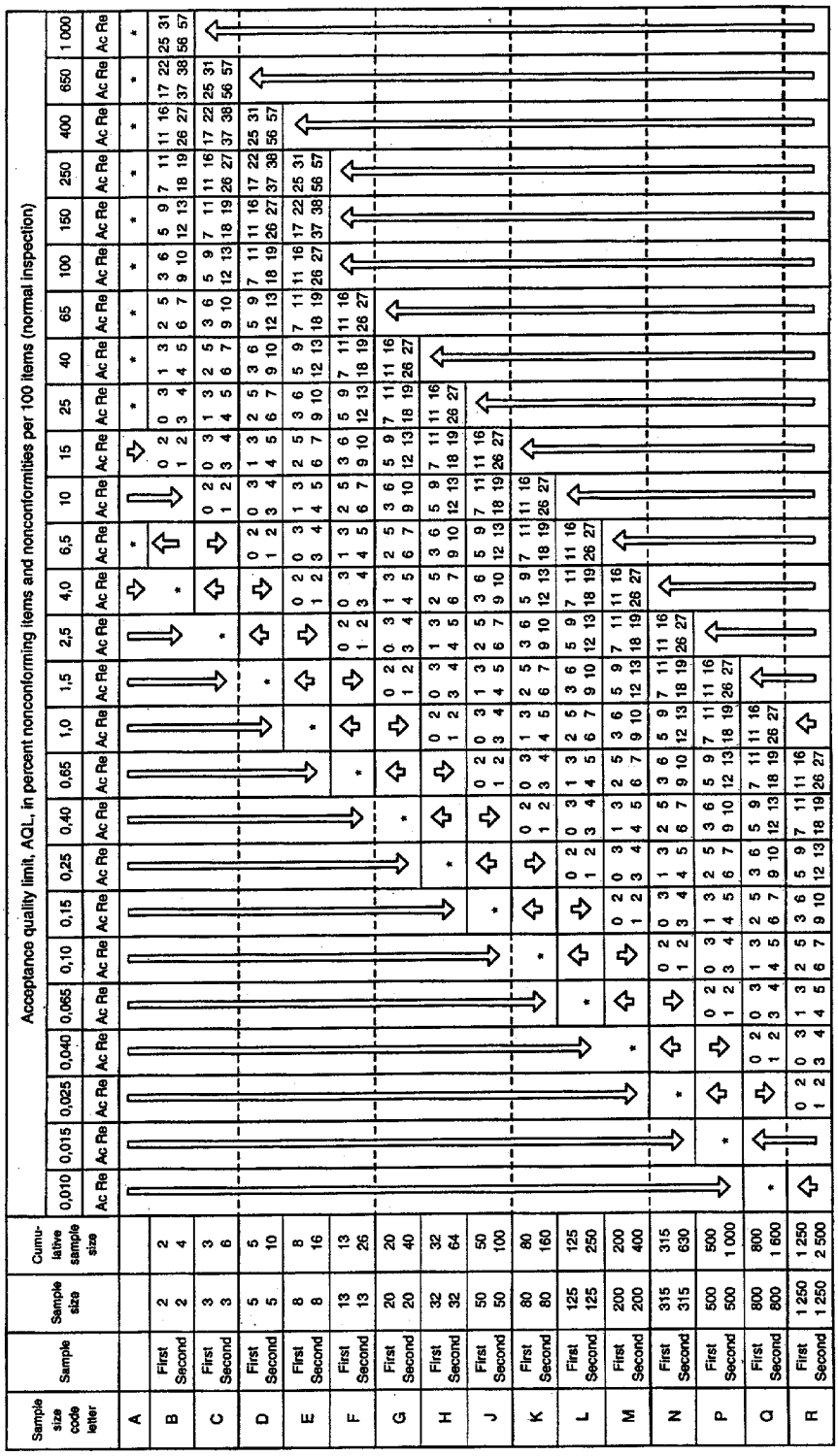


Table 3-A — Double sampling plans for normal inspection (Master table)



⇩ = Use the first sampling plan below the arrow. If sample size equals, or exceeds, lot size, carry out 100 % inspection.

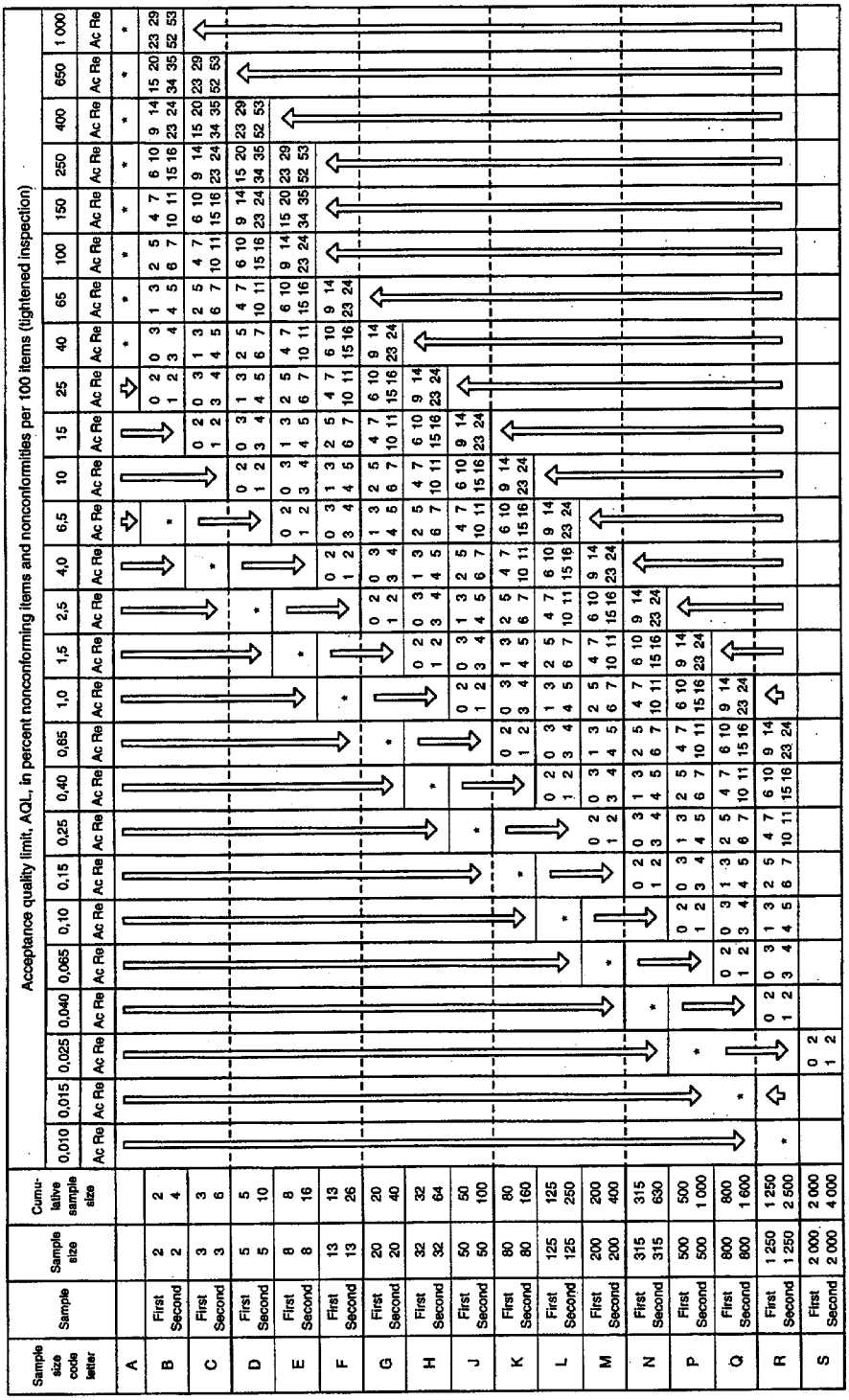
⇧ = Use the first sampling plan above the arrow.

Ac = Acceptance number

Re = Rejection number

* = Use the corresponding single sampling plan (or alternatively use the double sampling plan below, where available).

Table 3-B — Double sampling plans for tightened inspection (Master table)



⇩ = Use the first sampling plan below the arrow. If sample size equals, or exceeds, lot size, carry out 100 % inspection.

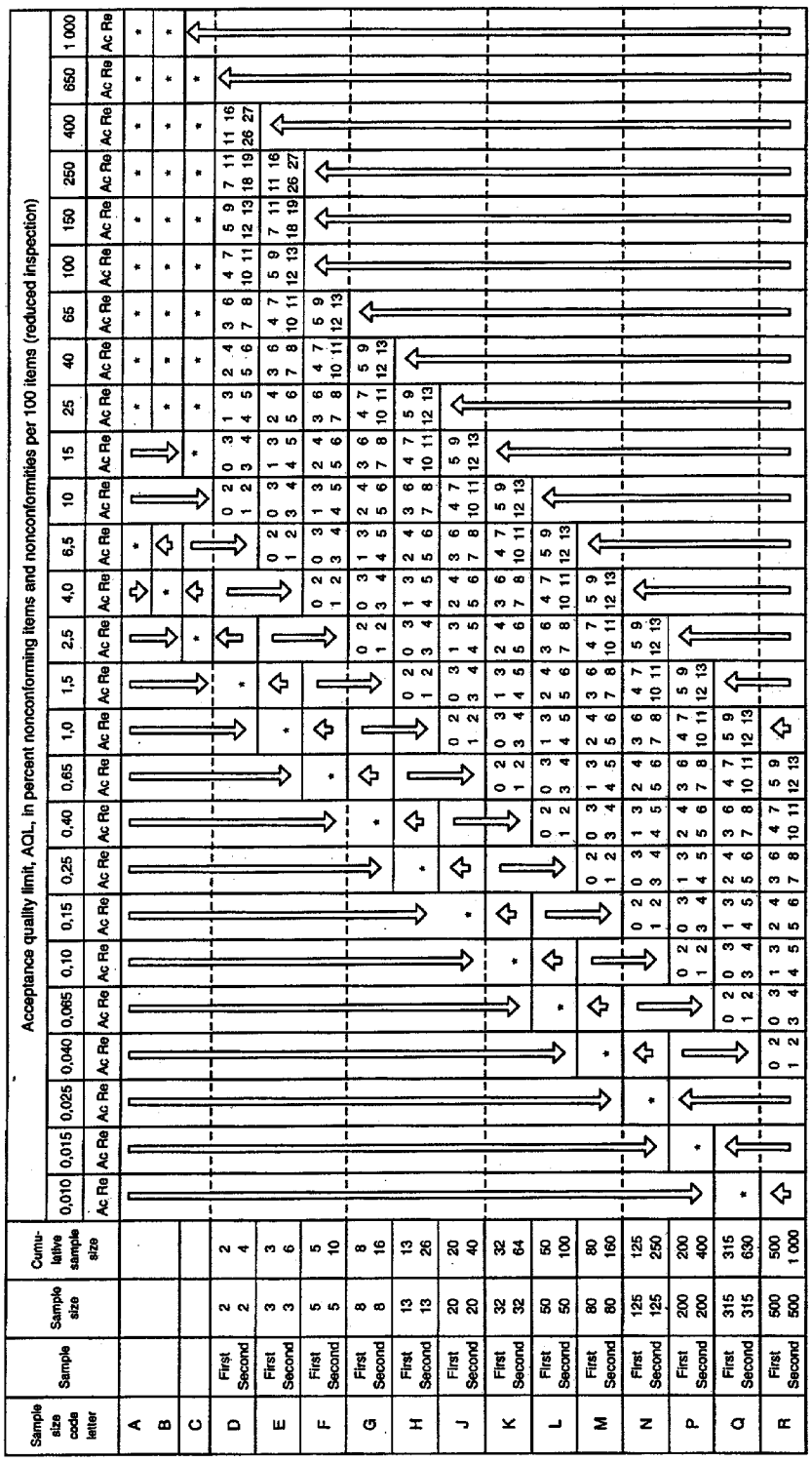
⇧ = Use the first sampling plan above the arrow.

Ac = Acceptance number

Re = Rejection number

* = Use the corresponding single sampling plan (or alternatively use the double sampling plan below, where available).

Table 3-C — Double sampling plans for reduced inspection (Master table)



⇩ = Use the first sampling plan below the arrow. If sample size equals, or exceeds, lot size, carry out 100 % inspection.

⇧ = Use the first sampling plan above the arrow.

Ac = Acceptance number

Re = Rejection number

* = Use the corresponding single sampling plan (or alternatively use the double sampling plan below, where available).

Table 8-A — Average outgoing quality limits for normal inspection (Single sampling plans)

Sample size code letter	Sample size	Acceptance quality limit, AQL, in percent nonconforming items and nonconformities per 100 items (normal inspection)																										
		0,010	0,015	0,025	0,040	0,065	0,10	0,15	0,25	0,40	0,65	1,0	1,5	2,5	4,0	6,5	10	15	25	40	65	100	150	250	400	650	1 000
A	2															18,4 14,8			42,0	68,6	97,1	158	224	326	470	733	1 085
B	3														12,3 10,5			28,0	45,7	64,7	106	149	218	313	489	723	1 102
C	5													7,36 6,70			16,8 16,0	27,4	38,8	63,4	89,4	131	188	293	434	661	
D	8												4,60 4,33			10,5 10,1	17,1 17,0	24,3	39,6	55,9	81,6	117	183	271	413		
E	13											2,83 2,73			6,46 6,32	10,5 10,5	14,9 15,1	24,4	34,4	50,2	72,3	113	167	254			
F	20										1,84 1,79			4,20 4,14	6,86 6,82	9,71 9,75	15,8 16,2	22,4	32,6	47,0	73,3						
G	32									1,15 1,13			2,62 2,60	4,28 4,27	6,07 6,08	9,90 10,0	14,0 14,3	20,4	29,4	45,8							
H	50								0,736 0,728			1,88 1,87	2,74 2,74	3,88 3,89	6,34 6,38	8,94 9,06	13,1 13,3	18,8	29,3								
J	80							0,460 0,457			1,05 1,05	1,71 1,71	2,43 2,43	3,96 3,98	5,59 5,63	8,16 8,27	11,7 12,0	18,3									
K	125						0,294 0,293			0,672 0,670	1,10 1,10	1,55 1,55	2,53 2,54	3,58 3,60	5,22 5,26	7,52 7,61	11,7 11,9										
L	200					0,184 0,183			0,420 0,419	0,686 0,685	0,971 0,971	1,58 1,59	2,24 2,24	3,26 3,28	4,70 4,73	7,33 7,41												
M	315				0,117 0,117			0,267 0,266	0,435 0,435	0,617 0,617	1,01 1,01	1,42 1,42	2,07 2,08	2,98 3,00	4,85 4,89													
N	500			0,0736 0,0735			0,168 0,168	0,274 0,274	0,388 0,388	0,634 0,634	0,894 0,895	1,31 1,31	1,88 1,89	2,93 2,94														
P	800		0,0460 0,0460			0,105 0,105	0,171 0,171	0,243 0,243	0,396 0,396	0,559 0,559	0,816 0,817	1,17 1,18	1,83 1,84															
Q	1 250	0,0294 0,0294			0,0672 0,0672	0,110 0,110	0,155 0,155	0,253 0,254	0,358 0,358	0,522 0,523	0,752 0,753	1,17 1,17															
R	2 000			0,0420 0,0420	0,0686 0,0686	0,0971 0,0971	0,158 0,158	0,224 0,224	0,326 0,327	0,470 0,470	0,733 0,734																

NOTE

Upper entries are for inspection for nonconformities per 100 items and are based on the Poisson distribution.
Lower entries are for inspection for percent nonconforming and are based on the binomial distribution.

Appendix IX: List of Reviewers/Invitees/ Participants at the Meetings Held to Develop the Contraceptive Procurement Manual

Ministry of Population Welfare

Mr. Shaukat Hayat Khan, Secretary, MoPW, Islamabad

Mr. Nayyer Agha, Ex. Secretary, MoPW, Islamabad

Mr. Aamanat Rasul, Director General, Procurement and Supply Operations, MoPW, Islamabad

Mr. Hamid Khalil, Director, MoPW, Islamabad

Mr. Muhammad Asghar, Deputy Director (PME), MoPW, Islamabad

Mr. Syed Asad Ali Naqvi, Deputy Director (PM), MoPW, Islamabad

Mr. Rana Umer Farooq, SO (Gen), MoPW, Islamabad

Mr. Ilyas Haider, Director, CW&S, Karachi

Mr. Ali Gohar Khan, DPWO, Islamabad

Ministry of Health

Mr. Khushnood Akhtar Lashari, Secretary Health, MoH, Islamabad

Dr. Rashid Jooma, Director General Health, MoH, Islamabad

Mr. Ghulam Rasool Dhotani, DDG (Reg.), MoH, Islamabad

Mr. Tanveer Alam, Director CDL, Karachi

Mr. Muhammad Masood, Deputy Drug Controller, Islamabad

Mr. Khushal Khan, MoH, Islamabad

PPRA

Mr. Hafeez ur Rehman, Managing Director, PPRA, Islamabad

Mr. Khalid Mehmood Lodhi, Director, PPRA, Islamabad

UNFPA

Mr. Malik Ahmed Khan, Senior Logistics Advisor, UNFPA, Islamabad

Technical Resource Facility

Mr. Farooq Azam, Team Leader, Technical Resource Facility, Islamabad

Mr. Inam-ul-Haq, Procurement & Capacity Strengthening Manager, TRF, Islamabad

National Programme for FP and PHC

Dr. Iqbal Lehri, National Coordinator, LHW Programme, Islamabad

Mr. Hamid Afridi, Deputy National Coordinator, LHW Programme, Islamabad

National MNCH Programme

Dr. Farooq Akhtar, National Programme Manager, MNCH Programme

Dr. Fayyaz Shaikh, Deputy Programme Coordinator, MNCH Programme

NACP

Mr. Rehman Shah, Procurement Specialist, Islamabad

Mr. Amir Maqbool, Procurement Specialist, Islamabad

PATH

Mr. Todd Dickens, Procurement Officer, Washington

USAID Pakistan

Dr. Muhammad Ahmed Isa, Reproductive Health Advisor, Islamabad

Mr. Khalid Mehmood, Programme Assistant

USAID | DELIVER PROJECT

Dr. Muhammad Tariq, Country Director, Islamabad

Mr. Shyam Lama, Senior Programme Manager, Arlington, USA

Mr. Iqbal Ahmad, Procurement Consultant, Islamabad

Mr. Saif ur Rab, IT/MIS Specialist, Islamabad

Mr. Usman Khalid, Administrative Officer, Islamabad

Dr. Khurram Shahzad, Logistics Programme Officer, Islamabad

Glossary of Definitions

Accountee	A legal term used in banking to describe the party (usually, the buyer) who is ultimately responsible for paying an amount guaranteed through a commercial "letter of credit."
Accrued	Accumulated through growth over time. For example, accrued penalties, accrued income.
Acceptable Quality Level (AQL)	A term used in quality assurance to classify defects into critical, major and minor categories.
Advising Bank	In documentary credits (L/Cs) – a commercial bank that notifies a beneficiary and/or transmits documents without taking on financial obligation.
Agent	A supply term for an independent contractor authorized by a manufacturer to promote and sell the manufacturer's products within a designated geographic area. Often an agent will contract to represent several manufacturers of non-competing products. Also used to describe an independent contractor or "agent" of an organization hired to inspect goods. Also, an independent contractor or "agent" hired to carry out procurement tasks.
Airway Bill	A shipping document issued by airlines and air-freight carriers when cargo is loaded on board an aircraft. It contains a description of the commodity being shipped, shipping instructions, terms and conditions of the shipment and applicable transportation charges.
Applicant	A legal term used in banking to describe a party (usually, the buyer) who is asking the bank to issue a commercial letter of credit in favour of a specified beneficiary (usually, the seller). Once the L/C has been issued, the "Applicant" becomes the "Accountee."

Arbitration A process in which a disagreement between two or more parties is resolved by impartial individuals, called arbitrators, in order to avoid costly and lengthy litigation. The International Chamber of Commerce maintains a court of arbitration as do many individual countries.

Authorized Person Any person who has been granted the power to authorize a transaction, or otherwise commit a Procuring Agency.

Award Notification A notification from the purchaser to the successful bidder recommended for a contract (generally based on the lowest evaluated bid).

Batch A manufacturing term meaning a single, uniform and homogeneous quantity produced from one compounding formulation, in one manufacturing and production operation and which has received entirely the same processing treatment. Used interchangeably with (manufacturing) Lot.

Batch Number The identification number assigned to a manufactured batch. See Lot or Batch Number.

Beneficiary A legal term used in banking to describe the party who is entitled to collect funds guaranteed by a commercial letter of credit upon presentation of stipulated documents - usually shipping and quality assurance documents.

Bid A procurement term describing a written offer for a quantity of Goods, works or services at a stated price based on a technical specification and specific terms and conditions. Bids are submitted to an intending purchaser by an intending seller in response to an invitation to bid.

Bidder An intending seller or supplier who submits a bid offering goods or services in response to an invitation or request for bids and offers.

Bid Documents The papers constituting a bid. Requirements are specified by the intending purchaser.

Bidding Documents A written description and set of terms and conditions of an intended purchase that is circulated by the intending buyer to prospective sellers.

Bid Offer A procurement term meaning an offer for goods or services submitted or received in response to a specific Invitation to Bid.

Bid Evaluation Committee A committee established by an Authorized Person or by the Federal Procurement Cell of a ministry to undertake evaluation of bids and quotations for procurement.

Bid Opening Committee A committee established by an Authorised Person or by the Federal Procurement Cell of a ministry to undertake opening of bids and quotations for procurement.

Bid Security A financial instrument that is used to guarantee compensation to the prospective buyer for inconvenience and expense if a winning bidder rescinds his offer after the bid is closed and an award is made to him. Each bidder provides an amount stated in the bidding documents with their bid submission; bid security is refunded promptly to all loosing bidders.

Bill of Lading A shipping document issued by a carrier (usually an ocean freight line) to a shipper that provides a written receipt for the goods, describes the conditions on which transport is made, and includes a written commitment to deliver goods at a stated destination to the lawful holder of the bill of lading.

Boat Note Report of a marine insurance survey conducted on board an incoming ship to assess the loss or damage of a consignment.

Boilerplate A selected text or part of a document that is repeatedly used without change.

Buffer Stock A term used in supply systems to describe extra quantities of stock kept on hand to cover unanticipated shortages - 25 % above expected usage is common.

Buyer	Party to a purchase transaction who pays a seller in exchange for goods. The Buyer does not necessarily have to be the recipient or consignee of the goods.
C&F Agent	A licensed professional agent appointed by an importer to clear its consignment from port and customs authority coming from abroad.
Carrier [carriage]	Any person who, in a contract of carriage, undertakes to perform or to procure the performance of carriage by rail, road, sea, air, inland waterway or by a combination of such modes.
Census Data	Statistics gathered about individuals in a national population; primarily numbers. Used by public health programmes to estimate annual commodity requirements and thus, determine the quantities that need to be purchased to meet these requirements.
Certificate of Free Sale	See "Lot Release Certificate."
Certificate of Inspection	A document often required with shipments of perishable or other goods; certification attests to the good condition of the merchandise immediately prior to shipment.
Certificate of No Objection	See No Objection Certificate.
Certificate of Origin	A shipping document certifying that the goods in a shipment have been produced in the stated country of origin.
Claim Bill	A bill prepared by an insured to lodge its claim for compensation.
Clean Report of Findings	A certificate issued by an inspection company stating that no discrepancies were found between specified criteria and the product as prepared for shipment. Pre-shipment inspection at the manufacturer's facility is recommended for most health sector goods. Some countries require routine (cursory) visual inspections at the port of loading for all goods entering the country.

Coercive Practice	Impairing or harming, or threatening to impair or harm, directly or indirectly, any party or the property of the party to improperly influence the actions of the party.
Cold Chain	A system of maintaining perishable medicines and vaccines at low temperatures from the time of manufacture until given to a child or adult. All vaccines and some medicines are sensitive to too much heat and some are sensitive to freezing.
Collateralize	A banking term meaning that money (or other security) is deposited or otherwise made available to cover a future payment. For example, letters of credit must be "collateralized."
Collusive Practice	An arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another party.
Commercial Bank	A "for profit" bank that provides services to the public.
Commercial Invoice	A shipping document issued by the seller, that identifies the buyer, and provides a description of the goods, the agreed price, delivery and payment terms, shipping date, mode of transport and an assigned invoice number.
Commodity	Commonly used to describe consumable products.
Competitive Bidding	Procurement process in which clearly stated product specifications and contract requirements are issued to multiple suppliers to solicit pricing and performance responses (bids). The purpose is to generate competition among several suppliers, which theoretically elicits the lowest possible prices. There are several types of competitive bidding procedures, including International Competitive Bidding, Local Competitive Bidding and Limited Competitive Bidding, Request for Quotation.
Conditional Discount; Cross Discount	A discount sometimes offered by potential suppliers bidding on two or more contracts simultaneously to apply only if two or more contracts would be awarded to him

Consignee	A term used in shipping that describes the party to whom something is entrusted, e.g., the "ship-to" party.
Confirming Bank	In documentary credits (L/Cs) – a commercial bank that promises to pay the beneficiary if the issuing bank defaults.
Consignment	A shipment containing part or whole of the contracted quantity of [imported] goods.
Context	Circumstances that surround and influence. As in programme context, market context.
Contract	An agreement entered into by two parties for the execution of certain activity, e.g., sale and purchase, construction, providing services, etc.
Contractor	A party having entered into a contract with the purchaser for supplying certain goods or performing certain works or providing certain services.
Convertible Currency	Currency that can be quickly bought and sold for other currencies; commonly traded internationally
Correspondent Relationship	The relationship between two banks when they have formally agreed to perform services for each other.
Corrupt Practice	Offering, giving, receiving or soliciting, directly or indirectly, anything of value to influence improperly the actions of another party.
Coverage	A health sector programme term for the estimated number of individuals actually served as a percentage of the target population.
Criteria	Specific points, standards, qualities, requirements against which something is judged.
Debarment	Shut out, exclude or prohibit [a firm] from participating in future competition for contracts

Defects - Critical, Major, Minor	Quality assurance terms used in evaluating a product's appearance, packaging and packing through visual examination and comparison with a precise description of requirements; results in a classification of any defects according to importance. There are published standards for how many defects can be allowed in a particular lot size under different assumptions. Used in condom procurement.
Defect, critical	A defect which, according to experience and professional criteria, makes a product dangerous or not viable for its intended use.
Defect, major	A defect that may make the product more difficult to use but does not have the safety and efficacy risk associated with a critical defect.
Defect, minor	A defect that is unlikely to affect usability but represents a departure from the specifications.
Determination	A decision that has been reached. For example, World Bank's no objection determination based on a review of draft bidding documents.
Demurrage Charges	Charges assessed against the consignee by a carrier, shipping agent or customs agent for delay beyond the time allowed or agreed upon for unloading and/or removal of goods from port facilities.
Development Partner	Financing institutions extending credits for development programmes of the GOB; in respect of HPSP, it is the World Bank (International Development Association).
Direct Contracting	A procurement method in which price and terms are settled with one chosen supplier without asking others for bids (e.g. without competition).

Direct Purchase	Used by the World Bank to mean purchase from a pre-selected source without competition, for example, when there is only one manufacturer of a required product. Sometimes used in government health programmes to mean purchasing vaccine and contraceptives directly from a manufacturer rather than through UNICEF or another third party.
Discrepancies	Used in banking and trade to mean lack of agreement with stated requirements and/or documents.
Documentary Evidence	Being, consisting of, or contained exclusively in documents.
Domestic Preference Allowance	A term used in World Bank procurement documents to describe a competitive advantage, expressed in a percentage, which is sometimes given to local manufacturers of goods competing for contracts against international sources.
Drug Formulary	A sub-set of "essential drugs" keyed to specific levels of health care [facility].
Duties	A tax charged by a government, especially on imports.
Eligibility (criteria)	Not excluded from competing for contracts in general by reason of nationality, debarment, lack of regulatory approval, etc.
Entity	A business and legal term to describe something that exists and functions as a separate and distinct body, for example, a corporation, a ministry of health, a committee.
Eligible Bid	A Bid that meets the basic eligibility criteria in a preliminary screening and which then goes forward for evaluation. Mandatory eligibility criteria may include registration as a company, possession of a business license etc. A Bid may also specify that a Bid Security for a specified amount and in a specified format be enclosed with the tender. If there is no Bid Security, the bid is "non-compliant" and, therefore, not "eligible" to go forward to the evaluation stage.

Essential Drugs [List]	A model list of around 300 drugs that provide for the health needs of the majority of the population
Estimate of Procurement Requirements	A judgment or approximate calculation of future commodity needs; quantification based on a forecast of use plus buffer stock requirements less existing stock and undelivered purchases.
Evaluated Cost	An offered price adjusted for corrections, discounts, domestic preference and usage factors.
Evaluation Criteria	Basis for judgment [announced in bidding documents] that will be used to select the winning bidder.
Expiry Date	A supply term for a date established by the manufacturer that appears on a drug, contraceptive or vaccine, beyond which the manufacturer will not guarantee the potency, purity, uniformity or bio-availability of the product.
Financial Instrument	A legal document that conveys financial commitment, such as a bond.
Financial Powers	The authority to spend given to an officer in the performance of his duties. In most Government systems, the amount of expenditure an officer may authorize is usually related to the level of his responsibility as well as to his seniority.
Forecast	A term used in public health programmes to describe a rational projection of future commodity demand based on population, birth rate and past consumption data.
Force Majeure	An event or affect that cannot be reasonably anticipated or controlled.
Fraudulent Practice	Any act or omission, including a misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain a financial or other benefit or to avoid an obligation
Generic	Applicable to all of a kind; common, not protected by trademark or patent. Used extensively in drugs procurement.

General Procurement Notice	Annual notice placed in UN publication Development Business about scope of anticipated ICB procurement to be financed by World Bank loans, amount and purpose of loans, and name and address of Borrower's agency responsible for procurement.
Specific Procurement Notice	Invitations to bid (or pre-qualify) for specific contracts advertised in newspapers, etc.
Good Manufacturing Practice (GMP)	An organized set of activities and performance standards covering personnel, premises and equipment, animal quarters and care, production, labelling, lot processing records and distribution records, quality assurance and quality control. A facility where GMP is followed can be relied upon to consistently produce good quality products that conform to established specifications because it maintains high standards of performance and adheres to written procedures. Used mainly in pharmaceutical, vaccine and medical device production.
Guarantor	A person or firm that guarantees to pay for someone else's debt if he or she should default on a loan or other financial obligation.
Harmonized Tariff System (HTS) Code	An international codification of merchandise for the purpose of classifying goods for tariffs and customs. The HTS assigns a 6-digit code for general categories of goods. Countries that use the HTS are allowed to define commodities at a more detailed level than 6 digits, but all definitions must be within that 6-digit framework.
Implementation Reqmt	Defined procedures and milestones associated with a project.
Implementing Agency	The agency responsible for carrying out project activities and monitoring progress toward defined milestones, goals and objectives.
INCOTERMS	International rules for the interpretation of the most commonly used terms in foreign trade published by the International Chamber of Commerce (ICC).

Indent	Request from the end-user for certain goods works or services that are to be purchased.
Inspection Agent	A party (or organization) appointed by the purchaser to conduct inspection of certain goods works or services.
Inspection Criteria	A term for the instructions and specifications against which an inspection agent will examine a shipment, usually before it leaves the manufacturer's site.
Inter-lineation	Notations written between the lines [of original bidding documents]
International Chamber of Commerce (ICC)	A non-governmental organization that serves world business by harmonizing trade practices, formulating terminology and establishing guidelines for importers and exporters.
International Competitive Bidding (ICB)	A procurement method that is initiated with a widely advertised notice of the bidding opportunity. Sealed bids are required based on clearly stated product specifications and performance expectations. Submissions are evaluated on their technical, commercial, contractual and financial merit, with awards going to the supplier making the most advantageous and cost-effective offer. All bids are final and no negotiation is allowed, except in regard to minor contractual points, after selection of a winning bid. The objective of the ICB is to provide all eligible prospective bidders with an equal opportunity to participate in the competition. Also known as open, or unrestricted, bidding.
International Shopping	A term used by the World Bank and others to describe a procurement process that relies on informal quotations and catalogueue pricing to establish a minimum level of competition. See Request for Quotation.
Inventory	Stock of goods available in a store or warehouse or go-down on a particular date.
Invoice	A document showing a short description of the cargo and its unit and total price; see "commercial invoice".

Joint Venture	A business enterprise in which two or more companies enter a temporary partnership.
Labelling	Used in the context of pharmaceuticals, vaccines and contraceptives to describe written text on packaging, boxes and accompanying leaflets. For products that are regulated by a government authority, labelling is considered an important part of the product and changes must be approved.
Lead Time	The time interval needed to complete a procurement cycle. It begins when the need for new stock is recognized and ends when that stock is received and available for issue. Alternate definition: Time from order to delivery; e.g., manufacturing and shipping time.
Letter of Commitment	An instrument committing funds for payment to a supplier against a contract.
Letter of Intent	A written expression of the purchaser made to the supplier to issue an award in favour of the supplier.
Letter of Credit	An arrangement by banks for settling commercial transactions; specifically, a written promise by a bank given to the Seller in accordance with the instructions (and cash deposit) of the Buyer to pay up to a given sum of money within a prescribed time limit when and if the Seller presents specified documents that give evidence of his performance.
Licensed Product	In the context of pharmaceuticals, vaccines and contraceptives, licensing by the regulatory authority of both the importing and exporting country implies a quality standard based on verified Good Manufacturing Practices, quality assurance data and appropriate oversight.
Liquidated Damages	In sales contracts, specified sum to be paid to the purchaser should the seller default on its obligation (usually pertaining to a delivery schedule).

Limited International Bidding (LIB) A procurement term describing the bidding process that limits participation to international and domestic suppliers that have been pre-qualified, pre-selected or short-listed in some manner by the purchaser. See Restricted bid and Pre-qualification.

Lot A supply term that can be used in two ways: Production Lot (see Batch-manufacturing) and Shipping Lot.

Lot or Batch Number A manufacturing term that describes the series of numbers or letters or both established to record production and control of a single, uniform and homogeneous quantity of drugs, chemicals or biologicals produced from one formulation, in one manufacturing and production operation and which has received entirely the same processing treatment.

Lot Release Certificate A regulatory term describing a certificate issued by the National Regulatory Authority of the country of manufacture that states the (manufacturing) lot number being shipped has been tested by the government's laboratory or checked in some other manner and found to be in conformity with the regulations of the country of manufacture and is released for sale. In some cases, this document may be titled "Certificate of Free Sale".

Lowest Evaluated Bid A bid (i) most closely conforming to evaluation criteria and other conditions specified in the bidding document; and (ii) having lowest evaluated cost.

Manufacturer's Representative A direct employee of a manufacturer with responsibility to promote the use of, provide information on and sell the manufacturer's products. In some cases, the representative also facilitates importation. Sometimes the term "agent" is used to convey the same relationship.

Margin of Preference See "Domestic Preference".

Marking Used in packing and shipping for the application of numbers, letters, labels, tags, symbols or colors for handling and identification during shipment and storage.

Material Deviation Used in evaluating bids to describe a significant and unacceptable difference from the requirements stated in bidding documents. More precisely, a material deviation is one that affects, in any way, the price, quantity, quality or delivery of the goods as required in the bid documents, or limits in any way the responsibilities, duties or liabilities of the bidder or any rights of the purchaser.

Merit Point System A numerical system used to evaluate and compare offers or bids. Points (based on a total of 100) are assigned according to how well an offer is judged to match evaluation criteria and preferences (which are stated by the purchaser in the original bidding documents) and its relative standing in the range of prices offered.

Middleman An independent broker who purchases product from a manufacturer or wholesaler and resells the product. This adds to the final cost of the product because the middleman's revenue from the transaction is the difference between his acquisition and holding cost and his sales price. Purchase of vaccine, pharmaceuticals and contraceptives through middlemen can increase the risk of receiving poor quality, mishandled or counterfeit product unless shipments are made directly from the manufacturer to the purchaser with appropriate original documentation.

National Competitive Bidding (NCB) A procurement method that follows the same format as International Competitive Bidding, but limited to local participants.

National Control Authority (NCA) See National Regulatory Authority. Both terms are currently in use.

National Control Laboratory (NCL) A laboratory advisory to the National Control Authority.

National Dailies Widely circulated daily newspapers whether in the native language or otherwise

National Regulatory Authority (NRA) An independent government entity responsible for establishing procedures to ensure that medicines (and biological products) intended for use in the country are safe, potent and effective.

Negotiated (Document)	Term used in international trade meaning that title to the Goods has been transferred to a new owner by delivery; normally requires transfer of funds from buyer to seller as well.
Negotiable Shipping Document	A document that establishes ownership of Goods and, therefore, has monetary value; usually, an ocean Bill of Lading.
Non-Governmental Organization	Organization that is not part of the structure of a government, but may perform complementary activities.
Non-responsive	Does not meet basic requirements; for bids this would include such critical items as signatures, bid security, completeness, agreement to terms and conditions, etc.
No Objection Certificate	A shipping/import document sometimes required by a country's customs, tax or other laws certifying that domestic manufacturers of pharmaceuticals, biologicals and medical devices have "no objection" to the import of a competing, similar or identical product.
No Objection Determination	A term used in World Bank procurement to describe the Bank's approval of draft bidding documents and recommendation for award.
Obstructive Practice	Delibertely destroying, falsifying, altering or concealing of evidence material to the investigation or making false statements to investigators in order to materially impede an investigation into allegations.
Offer	Used interchangeably with "bid" and "proposal".
Open Bid	A formal procurement procedure in which bids are accepted from any interested local or international source of the required product.
Packaging	A product's primary containers and coverings. In the context of injectables, vials and ampoules are the primary packaging, while boxes and bags containing several, up to 100, vials or ampoules are secondary packaging. In the context of tablets, blister packs or tins may be the primary packaging.

Packaging for bidding A term used by the World Bank and others for organizing very large, diverse schedules of goods to be purchased into groupings of like-items for bidding purposes.

Packing Assembling of items into a unit for shipment; carton, over-wrapping and insulation for protecting products against damage or deterioration during shipment.

Packing Requirements Identifies how product should be packed to withstand the handling and climatic conditions it will be subject to during transit. For heat sensitive pharmaceuticals and vaccines this includes instructions on the specific temperature range in which the product must ship and whether it can or cannot be frozen as well as information on the type of packaging and strength of packaging material to be used and inclusion of cold chain monitoring devices.

Packing List A schedule showing detailed packing information including: items and totals, number of units or items per box or crate, total number of boxes or crates with individual identification numbers thereof, shipping marks, total volume of the cargo, weights and dimensions per box or crate, etc.

Patent Exclusive rights granted by a government to an inventor to manufacture, use, or sell an invention for a certain number of years. US drug patents are usually good for 17 years.

Payment Terms A description of how, where and when payment will be made; for example, Letter of Credit, Cash in Advance, Open Account.

Performance Security A procurement term describing the financial instrument used to guarantee compensation to the Buyer for inconvenience and expense if the Seller does not perform, i.e., does not produce and ship the contracted goods or provide the contracted services within the stated period. The Seller puts up his own funds, often through a bank or an insurance company, to be held in reserve until the contract terms have been met.

Pharmacopoeia	A book published usually under the jurisdiction of the government and containing a list of drugs, their formulas and methods for making medicinal preparations, requirements and tests for their strength and purity and other related information.
Port of Entry	The port (including airport and land-port) designated in the bid and mentioned in the Bill of Lading or AWB where the consignment(s) under a contract is (are) to be carried to.
Port of Loading	The port (including airport and land-port) designated in the bid and mentioned in the B/L or AWB where the consignment is loaded into the ship for onward transportation to the Port of Entry.
Pre-qualification (of supplier)	A process of pre-approving suppliers for participation in bids based on a judgment of reliability, technical competence and financial stability.
Pre-qualification (of product)	A process of pre-determining that a specific product (usually a pharmaceutical or vaccine) of a specific manufacturer meets stated requirements and may be considered for purchase contracts in the approving country. Licensing by the National Regulatory Authority in the purchasing country automatically confers pre-qualification status.
Pre-shipment Inspection	Inspection of the contracted goods by or on behalf of the purchaser to ensure its conformity to the bid specification; this is done at the premises of the supplier or manufacturer prior to the goods being shipped.
Prior Review	World Bank terminology for its right to review and approve certain procurement decisions of a borrower before they are acted upon.
Procurement	The formal process of acquisition of goods, works, or services.
Procurement Agent	An individual or organization paid to act on behalf of a purchaser .

Procurement Entity	Body functioning as the purchaser in a commercial transaction (see entity, above).
Procurement Package	Goods of a similar nature that have been grouped together for procurement under a single contract in the interest of efficiency.
Procurement Plan	Package-wise schedule for purchasing activities including description of goods to be purchased, budget amount & source of funds; time period in which goods will be procured and the method of procurement; separate from "Operational Plan".
Procurement Requirements	A complete description of the product to be purchased, including technical attributes (especially manufacturing and quality assurance norms), programme specifications (including packaging, packing), shipping terms, payment terms, port of delivery, delivery date, quantity, documentation and any other relevant detail of the expected purchase.
Procurement Transaction	Agreements and actions of a Buyer and a Seller around a specific purchase; usually documented and legally binding.
Procurement Unit	The officer or team designated by a Procuring Agency to conduct procurement on its behalf.
Procuring Agency	Programme with responsibility to undertake procurement.
Proforma Invoice	An abbreviated invoice prepared by a supplier in advance of a sale or shipment. It gives a close approximation of weight and value of the shipment and other relevant data. Proforma invoices are used in some international procurement situations to support the purchaser's request to government authorities for import permits and foreign exchange. It is not binding on the seller until the order is confirmed.
Proposal	A procurement term that describes an offer to supply goods or services that is made in response to a specific Request for Proposal (RFP). Less formal in structure and process than sealed bidding (ICB, NCB, and LIB).

Proprietary Goods	Goods manufactured and sold only by a particular firm, usually under patent.
Protocol	A term used to describe a formal plan and specific methods for inspecting and testing goods.
Public Fund	As defined in SRO XXII of 2002, Chapter I, Section 2, Sub-section (k).
Public Procurement Regulatory Authority	An autonomous body responsible for prescribing regulations and procedures for public procurements by the Federal Government owned public sector organizations with a view to improve governance, management, transparency, accountability and quality ofpublic procurement of goods, works and services.
Public Sector Supply Service	An organization that contracts annually with manufacturers for large quantities of product which it then supplies in smaller quantities to individual clients in the public sector on a reimbursable, but non-profit basis. UNICEF and UNFPA are examples.
Pull System	A term used in distribution systems to indicate that peripheral levels request deliveries of specific kinds and amounts from a central level.
Procurement Office	The offices that will undertake and accomplish the task of procurement of goods under the HPSP; for the purpose of this manual, these offices are CMSD and DFP.
Push System	A term used in distribution systems to indicate that a central authority is sending goods to lower levels based on its own calculations of need rather than specific requests from the lower levels, i.e., it “pushes” goods to the lower levels.
Qualification (criteria)	An attribute that must be met or complied with that fits a competing firm for performing a specific contract.
Qualified Remarks	In international shipping, written list of deficiencies or damage noted by inspecting agent.

Quality Assurance	The combination of organized activities performed to demonstrate that a product meets quality criteria and specifications for its intended application. Quality assurance within the manufacturing organization provides confidence to the management. Quality assurance outside of the manufacturing organization provides confidence to the purchaser. In the context of pharmaceuticals, vaccine and contraceptives, it is typically undertaken before a shipment leaves the manufacturer's facility and/or, before the product is released for use in a country.
Quality Control	A manufacturing term that describes internal operational techniques and activities aimed at monitoring the manufacturing process and eliminating causes of unsatisfactory performance. Some quality control and quality assurance actions are interrelated.
Registration	A term used in regulating pharmaceuticals and vaccine; exact usage varies from country to country. It is often synonymous with Licensing but it can mean simply that the particulars about a shipment are recorded as it enters a country.
Request for Proposal	The term commonly used for bidding documents in the procurement of consultancy services.
Responsive Bid	A Bid that meets the technical requirements of the bidding document in the evaluation stage. Technically non-responsive bids do not go forward to the financial evaluation stage.
Reservations (to)	Negative findings, exceptions, disagreement, lack of approval.
Restricted Bidding	Bid procedures other than Open Competitive Bidding. Restricted Bidding refers to Bidding based on a shortlist of suppliers, on pre-qualification or on the various methods of procurement concerned with sole suppliers or a limiteded number of suppliers.
Retention Money	A certain percentage of the bill money payable to a contractor for the contracted goods works or services, that is held back retained by the purchaser, and paid after fulfillment of certain obligations by the contractor.

Revenue Funds, Budget	Funds, budget derived from a government's own activities [usually tax collection] rather than from development loans or grants such as HNPSP.
Safeguard	Protect, guard, keep safe.
Sampling	The process of selecting a small, representative quantity of materials from a much larger batch, shipment or consignment. Inspecting this representative sample enables judgment about the quality of the entire batch or shipment of products without having to inspect each individual unit.
Schedule of Requirements	Part of a bidding document that describes the quantity of goods and expected delivery time.
Sealed Bids	A procurement process where formal bids are submitted in sealed envelopes and held unopened until an appointed date and time, then opened and read out in public with bidders in attendance. See International Competitive Bidding, Local Competitive Bidding, Limited International Bidding.
Securities	Something given or deposited as surety for the fulfillment of a promise or an obligation, the payment of a debt, etc.
Seller	The party to a contract who offers goods, commits to seeing that they come into the Buyer's possession and (usually) receives payment from the Buyer. The Seller does not necessarily have to be the Supplier of the goods.
Shelf Life	The length of time designated by the manufacturer that a product may be stored without affecting its usability. Shelf life varies from product to product. The shelf life for a drug varies from 3-5 years. After the expiry date, the potency, purity and "bio-availability" of active ingredients are not guaranteed and drugs must be discarded and destroyed.
Shipping Marks	A mark or writing inscription that the purchaser instructs the seller to paint or write visibly and legibly on the outer side(s) of the boxes or crates so that the purchaser's goods can be easily seen and identified; usually this is instructed in the bidding document.

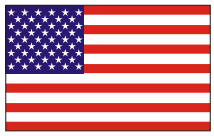
Shipping Terms	A description of how goods will be shipped, who is responsible for them at each stage of the process and who pays which costs. See INCOTERMS.
Short List	In procurement, a list of potential suppliers or contractors who have been qualified approved or pre-selected in some manner.
Sole Source	A procurement term used to describe purchasing from a single manufacturer without competition among potential suppliers; most often applies to items that are not available from any other source. Also see Direct Procurement.
Solicitation	A procurement term for the process of inviting bids or requesting proposals for the supply of a product or service; also used to refer to the document requesting bids or proposals.
Specification	Detailed, precise written description.
Specification Committee	A committee formed by an Authorized Person, Relevant Authority or a Federal Procurement Cell to undertake the preparation of specifications and documents for procurement.
Standard	Something that is established by authority as a rule for the measure of a quantity, weight, extent, value or quality. For example, the International Standards Organization (ISO) establishes "rules" for the vial closures commonly used for injectables.
Substantially Responsive	In World Bank procurement, a bid that contains no material deviations from or reservations to the terms, conditions and specifications in the bidding documents.
Supplier	The party who transfers goods out of his own control to a named recipient.
Surety	A person or firm that is legally responsible for the debt, default or delinquency of another.
Survey Report	A report of the insurance survey.

Target Population	A programme term for the total number of intended clients based on expected coverage rates.
Technical Evaluation Committee	A committee established to assist a Procurement Unit, Committee Relevant Authority, Bid Evaluation Committee or a Federal Procurement Cell to review documents and make technical evaluations
Threshold Level	A threshold is a point of entry or beginning. In World Bank terminology, it is a monetary level that determines whether a particular contract should be reviewed by World Bank prior to being invited and executed, and which GOB committee is responsible for bid evaluation; these levels are set in the loan or development credit agreement.
Trademark	A name, symbol, figure, letter, word or mark adopted and used by a manufacturer or merchant in order to designate his or her goods and to distinguish them from those manufactured or sold by others. Trademarks must be registered with a patent and trademark office to assure exclusive use by their owners.
Transparency	Openness and accountability in all activities and actions concerned with procurement.
Turnover	The number of times a particular stock of goods is sold and restocked during a given period of time; the amount of business transacted during a given period of time.
Uniform Customs and Practice for Documentary Credits (UCP)	A set of rules for cross-border transactions relating to Letters of Credit (also known as Documentary Credits and Documentary Letters of Credit) codified by the International Chamber of Commerce (ICC).
Unresponsive Bid	A procurement term used describe an offer that does not comply with the most basic instructions and requirements stated in the bidding documents provided by the purchasing organization. For example, an unresponsive bid may be one that is not signed, is in the wrong language or does not offer the required product(s).

Weighting (Factor) A system of units in a scale measuring weight (or value). In procurement, used to assign values to non-monetary items prior to comparing bids.

Wholesaler A supply term for a dealer who purchases supplies from a manufacturer on his own behalf and resells them for a profit.

Work Order Purchaser's communication to a contractor instructing him to undertake the obligations of a contract; usually a work order is part of the contract.



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